UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

PROFESSIONAL DRUG COMPANY, INC.

Plaintiff,

v.

PFIZER INC.,
PFIZER IRELAND PHARMACEUTICALS,
WARNER-LAMBERT COMPANY,
WARNER-LAMBERT COMPANY LLC AND
RANBAXY, INC.,

Defendants.

Civil Action No.

CLASS ACTION COMPLAINT AND JURY DEMAND

TABLE OF CONTENTS

I. INTRODUCTION 1

II. JURISDICTION AND VENUE 4

III. THE PARTIES 4

IV. LEGAL AND REGULATORY BACKGROUND 6

A. The Regulatory Structure for Approval of Generic Drugs and Substitution of Generics for Brand Name Drugs 6

1. The Hatch-Waxman Amendments 7

2. Paragraph IV Certifications 8

B. The Benefits of Generic Drugs 9

V. FACTS 10

A. A Short Primer on Statins 10

B. The Chemistry of Enantiomers 13

C. The Original Lipitor Patent: Warner-Lambert Obtains the '893 Patent 16

1. The Patent Specification Claims Atorvastatin, "the Corresponding Ring-Opened Acids Derived Therefrom" in Salt Form, and the R-trans and S-trans Enantiomers 17

2. The PTO Issues the Original Lipitor Patent 19

D. The Fraudulently Obtained Follow-On Patent: Warner-Lambert Obtains the '995 Enantiomer Patent by Repeatedly Misrepresenting the R-trans Enantiomer's Activity 19

1. The State of the Art: Knowledge of One Skilled in the Art of Statins in 1989 21

2. The Application: Warner-Lambert Fraudulently Claims the R-Trans Enantiomer is Ten Times More Active than the Racemate 23

3. The Initial Rejection: The PTO Determines the Claimed Compounds Are Anticipated By the '893 Patent 33

4. The Renewed Application: Warner-Lambert Submits the Roth Declaration, Again Falsely Claiming the R-Trans Enantiomer is Ten Times More Active than the Racemate 35

5. The Final Rejection: The PTO Determines the R-Trans Enantiomer is Anticipated 41

6. The Appeal: the PTO Determines the R-Trans Enantiomer is Prima Facie Obvious. 41

7. The '995 Patent Issues: PTO Relies on Biological Data to Overcome Obviousness 42

E. Warner-Lambert Intended to Deceive the PTO 44

1. Warner-Lambert Manipulated the Existing Biological Data to Show a Ten Fold Increase in Activity and Defendants Intentionally Presented False Information 44

2. Warner-Lambert Admits the Patent Specification Claims a Surprising Ten-Fold Increase in Activity 46

3. Warner-Lambert Intended for the PTO to Rely on the False Data and Claims 49

F. FDA Approval: The FDA approves Lipitor and the Original Lipitor Patent Provides Years of Patent Protection 49

1. The Orange Book Listings for the '893 and '995 Patents 49

2. The '893 Original Lipitor Patent Protected the Lipitor Franchise for Years 50

3. The 1997 Launch of Lipitor 53

G. Patent Litigation: Pfizer Sues for Infringement of the '995 Patent to Keep Generics off the Market 54

1. *Pfizer v. Ranbaxy*, 03-CV-209-JJF 54

2. *Pfizer v. Teva*, 07-CV-360 (D. Del. 2007). 57

3. *Pfizer v. Cobalt*: 07-CV-790 (D. Del. 2007). 57

4. *Pfizer v. Apotex*, 08-CV-7231 (N.D. Ill. 2008). 58

H. The '995 Reissuance Process Itself Becomes Another Chapter In the Scheme to Delay Generic Entry 58

1. Defendants Admit the Biologic Data is False 59

2. Lipitor's Commercial Success Has No Bearing on Whether the Invention Claimed by the '995 Patent is Obvious 62

I. Pfizer and Ranbaxy Conspire to Divide Markets and Cause Reissuance of the '995 Patent 64

VI. INTERSTATE COMMERCE 71

VII. MONOPOLY POWER AND MARKET DEFINITION 72

VIII. MARKET EFFECTS 73

IX. ANTITRUST IMPACT 75

X. CLASS ACTION ALLEGATIONS 75

XI. CLAIMS FOR RELIEF 78

XII. DEMAND FOR JUDGMENT 81

XIII. JURY DEMAND 82

I. INTRODUCTION

1. This antitrust action seeks damages for the delayed entry of generic versions of Lipitor (atorvastatin calcium). Although the original compound patent for Lipitor expired March 24, 2010, generics remain foreclosed until the end of November 2011. Why? Pfizer has successfully implemented a unlawful scheme to delay generic entry by (i) obtaining through fraud a follow-on patent for Lipitor, (ii) listing that patent in the FDA Orange Book in order to block generic entry, (iii) filing sham litigation on this follow-on patent and other process patents known to have no merit, and (iv) ultimately turning to the first potential generic entrant, Ranbaxy, and cutting a deal with it to delay entry into, and allocate the market for, atorvastatin. Defendants thereby delayed, and continue to delay, access to less expensive generic alternatives.

2. In 1987, Warner-Lambert obtained the original compound patent for Lipitor, U.S. patent 681,893 (the "'893 Original Lipitor Patent"). The '893 patent included protection for various enantiomer forms, including the isolated enantiomer of atorvastatin which, when formulated into a calcium salt, is Lipitor.

3. Two years later, Warner-Lambert sought even longer patent exclusivity for Lipitor. Warner-Lambert applied for a patent specifically for the isolated enantiomer in various forms, including the calcium salt. At first, the United States Patent and Trademark Office rejected the effort: the follow-on patent could not be granted because the isolated R-trans enantiomer forms were either anticipated by (i.e. already covered by), or obvious in light of, the '893 patent (since a discrete number of isomers were known and disclosed in the '893 patent, and the desirability and mechanics of isolating these isomers were well known in the craft).

4. Warner-Lambert then chose a different tactic to obtain super-long patent life for Lipitor: it defrauded the PTO. To circumvent the obviousness objection, Warner-Lambert

falsely represented that it had unexpectedly discovered that the isolated enantiomer form did not have, as one would expect, only twice the biologic activity of the racemate, but was *ten times* more effective in inhibiting the production of cholesterol than its non-isolated racemate compound. This was not true. Warner-Lambert's false representation was the basis upon which the PTO granted the follow-on enantiomer patent.

5. Warner-Lambert's false representation that the particular, isolated enantiomer had ten times the biologic activity of the racemate was highly material and made with intent to defraud. Recent patent lawsuits reveal Warner-Lambert's abuses before the PTO. For example, the first ostensibly completed data presentation used by Warner-Lambert to support the ten-fold representation was, in fact, an unscientific mish-mash of data points selected ad hoc from over a dozen separate tests performed on different formulations over a two-year period. The ten-fold powered enantiomer "invention" was only "discovered" after Warner-Lambert lawyers instructed the lead scientist to go back through years of data and find something "surprising." A second, ostensibly complete and confirmed data submission was in fact the partial results of a single selected test so methodologically flawed (e.g., the drug wasn't even dissolved into a solution before testing) that no reasonable chemist would have relied on the bizarrely conflicted quantitative results it reached. For these introductory purposes, these two examples are sufficient to describe the parade of scientific abuse and misrepresentations made by Warner-Lambert to acquire the super-long extension of patent life for Lipitor.

6. After fraudulently procuring the U.S. patent number 5,273,995 (the "'995 patent"), Pfizer listed that patent in the FDA Orange Book, and litigated infringement actions against generic companies that otherwise would have been able to enter the market upon the March 2010 expiration of the original Lipitor patent.

7. Years into its efforts to prosecute sham litigation alleging infringement of the '995 patent, Pfizer faced a dramatic reduction in future revenue with the loss of exclusivity of Lipitor due to the '995 patent having been declared invalid. So Pfizer turned to its long adversary, Ranbaxy, and the two entered into an unlawful agreement to delay the entry of generic versions of Lipitor into the United States for up to 20 months after its patents had expired.

8. The fundamental terms of this agreement were that Ranbaxy would not enter the United States market with its Lipitor generic until November 2011. By agreeing to delay entry, Ranbaxy maintained the bottleneck, preventing other generics from entering the United States market until the summer of 2012 or later. In return, Ranbaxy was authorized to sell generic Lipitor in several other countries. Pfizer also agreed to drop its challenge of Ranbaxy's current sale of a generic version of Lipitor in several countries, and Pfizer cancelled a Ranbaxy judgment debt arising from another case.

9. In order to disguise the anticompetitive nature of this agreement, Pfizer initiated litigation against Ranbaxy for infringement of two process patents, even though Pfizer and Ranbaxy both knew (from previous court rulings) that Pfizer did not have standing to bring an infringement case using those two process patents; since Ranbaxy had already been enjoined from manufacturing generic Lipitor and therefore could not, as a practical matter, infringe the process patents, a federal court would not have power to hear this "new" case. This ruse over the process patents was "resolved" in three months, between the original filing in March of 2008 and the dismissal in June of 2008.

10. The over-arching scheme by Pfizer, and the later deal between Pfizer and Ranbaxy, unlawfully delayed entry of less expensive, AB-rated generic drugs into the market for

atorvastatin calcium from March of 2010 through at least the end of November of 2011. Annual sales of Lipitor in the United States exceed $5 billion. By the time a trial of this matter is conducted, it appears that generic entry of Lipitor will have been foreclosed unlawfully for about two years. The judgment, once entered, should be trebled.

II. JURISDICTION AND VENUE

11. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§1 and 2, and sections 4 and 16 of the Clayton Act, 15 U.S.C. §§15 and 26, to recover threefold damages, costs of suit and reasonable attorneys' fees for the injuries sustained by Plaintiff and members of the Direct Purchaser Class resulting from Defendants' unlawful foreclosure of generic entry into the market for atorvastatin calcium. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1337(a), and 15 U.S.C. § 15.

12. Defendants transact business within this district and carry out interstate trade and commerce, in substantial part, in this district. Venue is appropriate within this district under section 12 of the Clayton Act, 15 U.S.C. § 22, and 28 U.S.C. §1391(b) and (c).

III. THE PARTIES

13. Plaintiff Professional Drug Company, Inc. is a Mississippi corporation with its principal place of business in Biloxi, Mississippi. During the class period, as defined below, Professional Drug purchased Lipitor directly from Warner-Lambert and/or Pfizer. Professional Drug was injured as a result of Defendants' unlawful conduct.

14. Defendant Pfizer, Inc. is a corporation organized and existing under the laws of the State of Delaware and has a place of business at 235 East 42nd Street, New York, New York 10017. Pfizer, Inc. prosecuted infringement litigation for U.S. patent number 5,273,995 " '995 Patent") in order to delay generic entry into the market for generic atorvastatin calcium. Pfizer, Inc. knew the '995 Patent was invalid and/or unenforceable.

15. Defendant Pfizer Ireland Pharmaceuticals is a partnership organized and existing under the laws of Ireland, with registered offices at Pottery Road, Dun Laoghaire, Co. Dublin, Ireland. Pfizer Ireland Pharmaceuticals is the exclusive licensee for the '995 patent. Pfizer Ireland knowingly participated in Pfizer's attempts enforce the '995 patent. Pfizer Ireland Pharmaceuticals is a wholly owned, indirect subsidiary of Pfizer, Inc. Pfizer, Inc.

16. Defendant Warner-Lambert Company is a corporation formerly organized under the laws of the State of Delaware with offices for service of process at 235 East 42nd Street, New York, New York 10017. In 1997, Warner-Lambert and Pfizer began co-promotion of Lipitor. In mid-2000, Warner-Lambert Company became a wholly-owned subsidiary of Pfizer Inc. At the end of 2002, Warner-Lambert Company became a Delaware limited liability company and changed its name to Warner-Lambert Company LLC. Warner-Lambert knowingly controlled all activities of the applicant before the PTO in connection with the prosecution of the '995 Enantiomer Patent.

17. Warner-Lambert Company and Warner-Lambert Company LLC are collectively referred to as "Warner-Lambert." "Warner-Lambert" includes, but is not limited to, Warner-Lambert employees Bruce D. Roth, Joan Thierstein, and Jerry F. Janssen.

18. Defendants Pfizer, Pfizer Ireland Pharmaceuticals, and Warner-Lambert are collectively referred to as "Pfizer."

19. Defendant Ranbaxy, Inc. is a corporation organized and existing under the laws of the State of Delaware, and has a place of business located at 600 College Road East, Princeton, New Jersey, 08540 ("Ranbaxy"). Upon information and belief, Ranbaxy was formerly known as Ranbaxy Pharmaceuticals, Inc., and is a wholly owned subsidiary of Ranbaxy Laboratories.

20. The actions of Pfizer and Ranbaxy were in furtherance of the alleged wrongdoing described herein, and were authorized, ordered, or done by Defendants' officers, agents, employees, or representatives while actively engaged in the management of Defendants' affairs.

IV. LEGAL AND REGULATORY BACKGROUND

A. The Regulatory Structure for Approval of Generic Drugs and Substitution of Generics for Brand Name Drugs

21. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers who create a new drug product must obtain the approval of the FDA to sell the new drug by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

22. When the FDA approves a brand name manufacturer's NDA, the brand manufacturer may list any patents that the brand manufacturer believes could reasonably be asserted against a generic manufacturer who makes, uses, or sells a generic version of the brand name drug prior to the expiration of the listed patents in the FDA's book of Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book." Patents issued after NDA approval may be listed within 30 days of issuance. 21 U.S.C. §§ 355 (b)(1) & (c)(2). The FDA relies completely on the brand name manufacturer's truthfulness about patents' validity and applicability; the FDA does not have the resources to check the manufacturer's representations for accuracy or trustworthiness; it does not check the facts supplied to it by the brand-name manufacturer. After the NDA is approved, the brand-name manufacturer may list other new patents in the Orange Book as related to the NDA, if the brand-name manufacturer similarly certifies that the new patents claim either the approved drug or its approved uses.

1. The Hatch-Waxman Amendments

23. The Hatch-Waxman Amendments enacted in 1984 simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). A generic manufacturer seeking approval to sell a generic version of a brand name drug may now file an abbreviated new drug application (ANDAs). ANDAs rely on the scientific findings of safety and effectiveness included in the brand name drug manufacturer's original NDA, but must show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand name drug – that is, that the generic drug is bioequivalent to the brand name drug. The FDA assigns generic drugs that are bioequivalent to branded drugs an "AB" rating[1].

24. The FDCA and Hatch-Waxman Amendments operate on the presumption that bioequivalent drug products containing identical amounts of the same active ingredients in the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another. Thus, bioequivalence demonstrates that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B).

[1] Generic manufacturers can also seek approval of non-AB-rated generics. The FDCA permits "hybrid" applications that are neither full NDAs containing safety and efficacy data, nor ANDA applications showing that the proposed product is the "same" as the NDA product. 21 U.S.C. § 505(b)(2). Drug products approved under this section use a safe and effective active pharmaceutical ingredient, but modify the drug product in some way so that it differs from the original NDA product, either in dosage form, strength, route of administration, formulation, dosing regimen, or indication. These non-AB-rated generics are not bioequivalent to the innovator product. See 21 CFR 314.54.

25. Through the Hatch-Waxman Amendments, Congress sought to expedite the entry of legitimate (non-patent infringing) generic competitors, thereby reducing healthcare expenses nationwide. Congress also wanted to protect pharmaceutical companies' incentives to create new and innovative products.

26. The Hatch-Waxman Amendments achieved both goals, substantially advancing the rate of generic product launches, and ushering in an era of historic high profit margins for brand name pharmaceutical companies. In 1983, pre-Hatch Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic versions available; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generics totaled $21.6 billion and generic drugs accounted for 18.6% of prescriptions. By 2009, total prescription drug revenue had soared to $300 billion and generic drugs accounted for 75% of prescriptions.

2. Paragraph IV Certifications

27. To obtain FDA approval of an ANDA, a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any patents listed in the Orange Book. Under Hatch-Waxman, a generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the brand name drug has been filed with the FDA (a "Paragraph I certification");

ii. that the patent for the brand name drug has expired (a "Paragraph II certification");

iii. that the patent for the brand name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or

iv. that the patent for the brand name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

28. If a generic manufacturer files a Paragraph IV certification, a brand name manufacturer has the ability to delay FDA approval of an ANDA simply by suing the ANDA

applicant for patent infringement. If the brand name manufacturer initiates a patent infringement action against the generic filer within 45 days of receiving notification of the Paragraph IV certification, the FDA may not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. The FDA may grant "tentative approval," but cannot authorize the generic manufacturer to go to market.

29. As an incentive to spur generic companies to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification gets a period of protection from competition with other generic versions of the drug. For Paragraph IV certifications made prior to December 2003, the first generic applicant is entitled to 180 days of market exclusivity. Meaning, the first approved generic is the only available generic for at least six months.

30. FDA regulations unintentionally provide incentives for brand name manufacturers to list patents in the Orange Book – even if such patents are not eligible for listing – and sue any generic competitor that files an ANDA with Paragraph IV certifications – even if the competitor's product does not actually infringe the listed patent(s) – in order to delay final FDA approval of an ANDA for up to 30 months.

B. The Benefits of Generic Drugs

31. Typically, AB-rated generics cost much less than their branded counterparts. Over time, as more generic equivalents compete with each other, prices decline even further. Since passage of the Hatch-Waxman Amendments, every state has adopted substitution laws that either require or permit pharmacies to substitute AB-rated generic equivalents for branded prescriptions (unless the prescribing physician has specifically ordered otherwise).

32. Every link in the prescription drug chain has an incentive to choose less-expensive generic equivalents. As a result of federal reimbursement rules and the industry pricing structure, pharmacies typically earn a higher markup on generics. Private health insurers similarly offer direct incentives to pharmacies to substitute cheaper generic products for more expensive branded ones. Health insurers are contractually obligated to pay for the bulk of their members' prescriptions, whether filled with branded or generic drugs, so offer their members lower copays for generic drugs in order to encourage the use of generics. Members also face the threat of increased health insurance premiums if branded prescription drug costs continue to rise.

33. Once a generic equivalent hits the market, the generic quickly overtakes sales of the branded drug. More than 90 percent of prescriptions for drugs that are available in both branded and generic forms are filled with a generic. The speed with which generic drugs take over the market appears to be increasing: in a sample of drugs losing patent protection between 1991 and 1993, generics on average held a 44 percent market share after one year; by 2008, generic versions could capture as much as 86 to 97 percent of the market within the first month.

34. Branded manufacturers are well aware of generics' steady erosion of their previously monopolized market. Branded manufacturers thus seek to extend their monopoly for as long as possible, sometimes resorting to any (illegal) means possible.

V. FACTS

A. A Short Primer on Statins

35. Lipitor belongs to a class of drugs called statins. Discovered in the 1970s, statins lower cholesterol by successfully inhibiting the liver enzyme 3-hydroxy 3-methylglutrayl-coenzyme A reductase ("HMG-CoA reductase"). HMG-CoA reductase controls the rate at which our bodies produce cholesterol; inhibiting HMG-CoA reductase reduces the production of

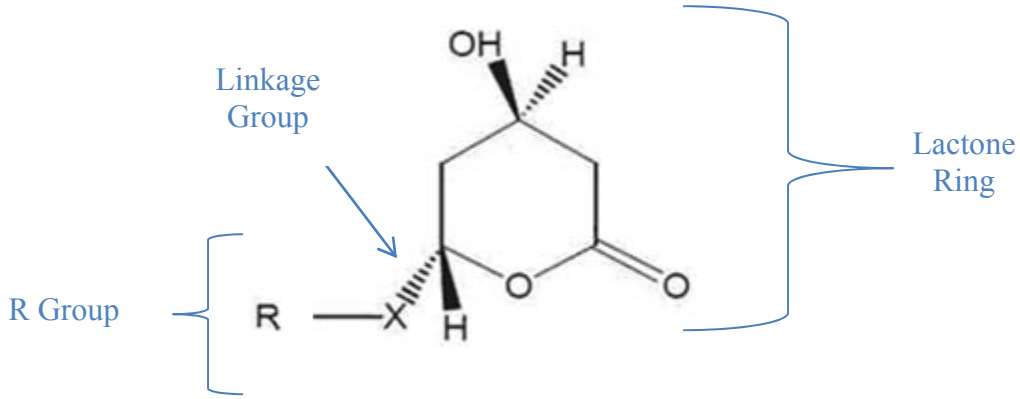
cholesterol. High levels of cholesterol are thought to cause serious health problems, including coronary heart disease and atherosclerosis in some populations.

36. Efforts to reduce cholesterol levels are a big business: by 1997, five of the largest pharmaceutical companies sold six different brand-name statins. In 2002, almost one in ten Americans aged 20 and older took a statin. In 2004, sales of statins topped $15.5 billion, and comprised 6.6% of all prescription drug sales.

37. Branded statins cost between $2.50 and $5.00 for a single daily pill ($75 to $150 a month, $900-$1,800 a year); generic statins cost markedly less, sometimes less than $1 a day.

38. Statins consist of three structural parts: a lactone ring, a linkage group (denoted as "X"), and a group or groups connected to the linkage group (referred to herein as an "R group").

Figure 1: Generalized Structure of Statins[2]

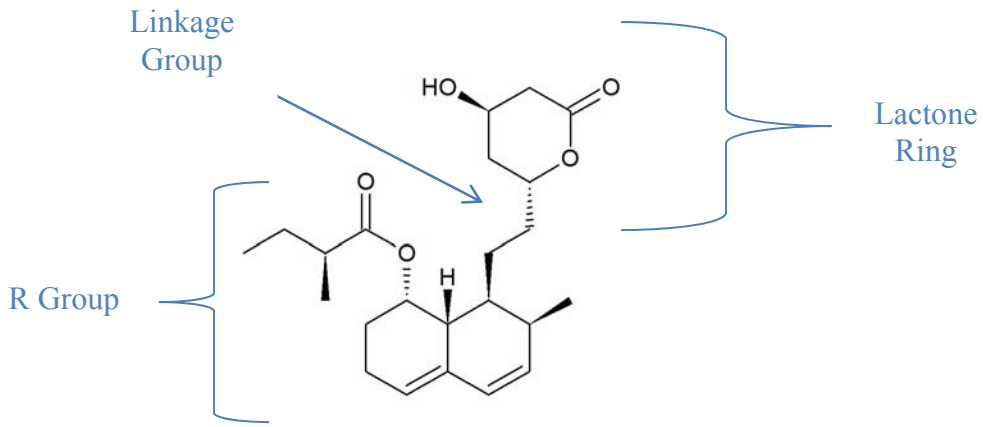


39. The R group for the well-known statins can contain one or more single rings or fused rings, and other substituent groups.

40. In the 1970s, researchers discovered that mevastatin, naturally occurring in red yeast and rice, inhibited cholesterol synthesis.

[2] The three-dimensional structure of molecules can be represented pictorially in two dimensions using the following symbols to represent the orientation of the atoms in space: ◥ (solid wedge) indicates that the molecule is projecting out of the page; ⁞ (dashed wedge) indicates that the molecule is projecting behind the page; — (solid line) indicates that the molecule is in the plane of the paper.

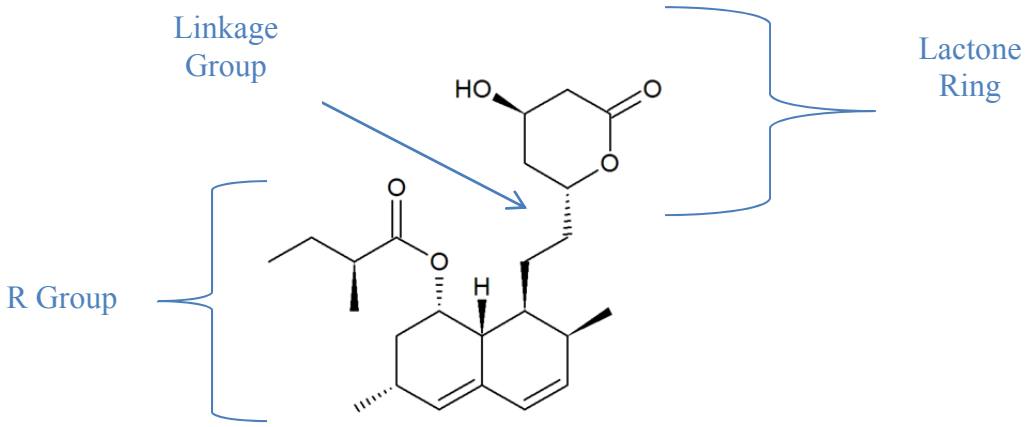
Figure 2: Mevastatin



41. Mevastatin contains the lactone ring as shown in Figure 1, a linkage group, X (shown as ), and an R group of two fused rings with substituents. One of the fused rings contains a methyl group (-CH_3, shown as ) on the right ring and an additional O-linked substituent group on the left ring.

42. Around the same time, researchers discovered lovastatin, naturally occurring in red yeast rice and Oyster mushrooms, was another highly potent HMG-CoA reductase inhibitor. In the early 1980's Merck sought and gained approval for Mevacor, a brand name version of lovastatin, the first statin available in the United States.

Figure 3: Lovastatin



43. The structure of lovastatin is very similar to mevastatin. Lovastatin also contains a lactone ring and an R group joined to the lactone ring by a linkage group. Lovastatin's R group is the same as mevastatin's R group but with one additional methyl group.

44. Research in the 1980s demonstrated that statin molecules with opened lactone rings were highly potent cholesterol synthesis inhibitors – often more potent than the closed lactone ring forms of the same molecules.

45. In the early 1980s, Warner-Lambert sought to enter the market by developing a "me-too" version of the already-identified statins. Researchers at Warner-Lambert came up with a formulation that used the same lactone ring as mevastatin and lovastatin but contained different linked substituents as the R group. Warner-Lambert called their new statin "atorvastatin."

B. The Chemistry of Enantiomers

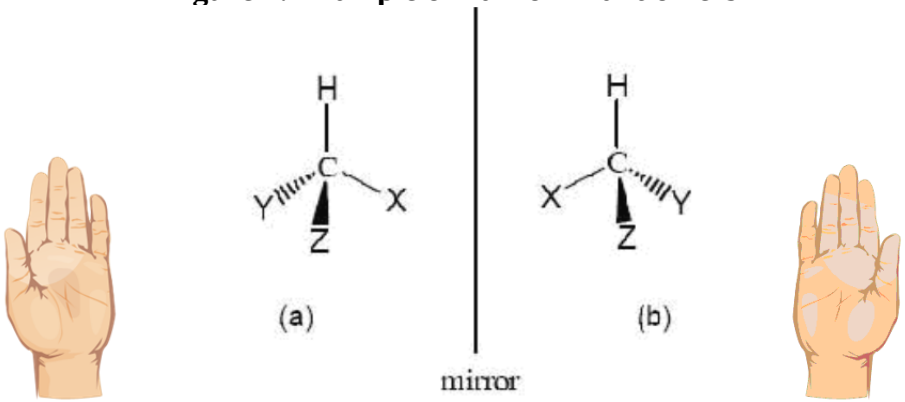
46. To understand how the Original Lipitor Patent covered the compound Roth and Warner-Lambert later sought to patent in the '995 Patent, some background on the chemistry of enantiomers is helpful.

47. Isomers are two or more compounds with the same chemical formula (that is, containing the same atoms) but different arrangements of atoms. Stereoisomers are isomers in which the same atoms are bonded together, but where the three-dimensional configuration of those atoms differ.

48. Enantiomers are stereoisomers that are mirror images of each other and cannot be superimposed; the same atoms, bonded together in the same way, but one is arranged as a reflection of the other. Consider, for example, a left hand and a right hand.

49. Images (a) and (b) in Figure 5 below are enantiomers (where the carbon atom is the chiral center around which a compound's structure is built).

Figure 4: Example of Pair of Enantiomers



50. Pairs of enantiomers have many identical chemical and physical properties, such shared melting points, solubility, and colors. Other properties, such as biological properties, may be vastly different.

51. Enzymes, including the cholesterol producing HMG-CoA reductase, typically display a preference for interacting with one enantiomer over the other. It is common for one enantiomer to have all, or most, of the biological activity. The other enantiomer will have little or no biological activity.

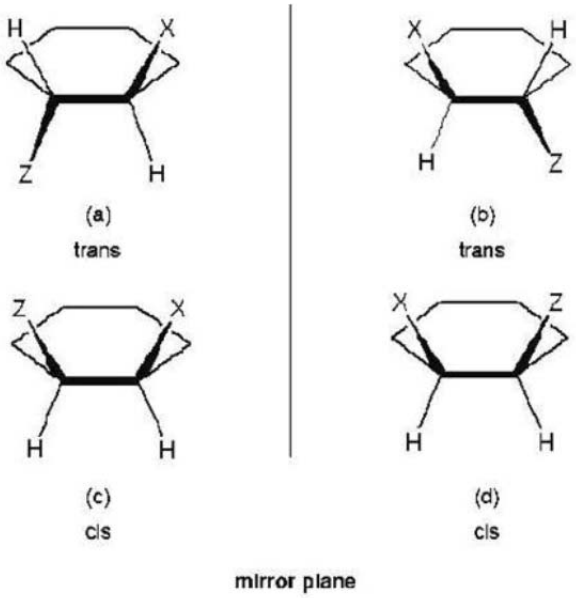
52. Enantiomers can be distinguished from one another by their effect on the rotation of polarized light. Enantiomers reflect polarized light in either a clockwise direction (right, denoted with a "+") or a counter-clockwise direction (left, denoted with a "-"). An unequal mixture of two enantiomers is optically active; the degree of optical rotation reflects the percentage of each enantiomer in the mixture. When equal mixtures of two enantiomers are present, called a *racemic mixture* or *racemate*, the optical rotations of the enantiomers cancel each other.

53. To differentiate enantiomers on paper, each enantiomer is assigned a configuration based priority rules that rank the atoms or substituent group of atoms that are

attached to the chiral center. If the priority proceeds in a clockwise direction, the enantiomer has an 'R' (right) configuration; if the arrangement is counter-clockwise, the enantiomer has an 'S' (left) configuration.

54. In addition to R/S and +/- configurations, a molecule's configuration can also reference the location of the substituent atoms or groups of atoms relative to each other. An arrangement where both the major substituents lie on the same side of the plane of reference is called a *cis* arrangement. An arrangement where the major substituents appear on the opposite sides of the plane is called a *trans* arrangement. The placement of X and Z in the figure below demonstrates these cis and trans arrangements.

Figure 5: Examples of Cis and Trans Arrangements



55. The lactone rings found in statins have two chiral centers, one at the carbon with the hydroxyl group and the other at the carbon attached to the linkage group. Rings containing two chiral centers give rise to four possible isomers: the R-cisisomer, the S-cisisomer, the R-transisomer, and the Strans-isomer.

56. At the time Warner-Lambert and Roth were developing Lipitor, the preferred configuration for the lactone ring in a statin – the configuration offering the highest level of cholesterol inhibition – was the R-trans configuration.[3] Both mevastatin and lovastatin have lactones in the R-trans configuration. In the case of HMG-CoA reductase inhibitors, the R-trans enantiomer appeared to be the active enantiomer that inhibited HMG-CoA and reduced the production of cholesterol.

57. Consistent with conventional thinking, Warner-Lambert's application for the Original Lipitor Patent contemplated the trans-form of compounds sharing the same structural formula, including atorvastatin. The application contemplated atorvastatin in a variety of formulations, including calcium salts.

C. The Original Lipitor Patent: Warner-Lambert Obtains the '893 Patent

58. On March 30, 1986, Warner-Lambert filed U.S. Patent Application No. 868867 for a group of compounds and pharmaceutical compositions useful as hypercholesterolemic and hypolipidemic agents. The patent application was entitled "Trans-6-[2-(3- or 4-Carboxamido-Subsituted Pyrrol-1-yl)alkyl]-4-Hydroproxypyran-2-one Inhibitors Of Cholesterol Synthesis." This application eventually resulted in U.S. Patent No. 4,681,893 (the "Original Lipitor Patent" or the " '893 Patent").

59. Dr. Bruce David Roth applied for the '893 patent. Roth invented Lipitor. (Roth is not named as a defendant in this action.) Roth was at all relevant times, a leader of the drug discovery team at Warner-Lambert that developed Lipitor. He is the named inventor and patent applicant of the '893 and '995 patents; both patents issued to Roth and were assigned to his

[3] See, *e.g.*, Alberts, A. *et al., J. Proc. Natl. Acad. Sci. USA* 1980, *77:*3957; Stokker, G.E., *et al., J. Med. Chem*. 1985, 28:347-358; Stokker, G.E. et al., *J. Med. Chem,* 1986, 29: 849-852.

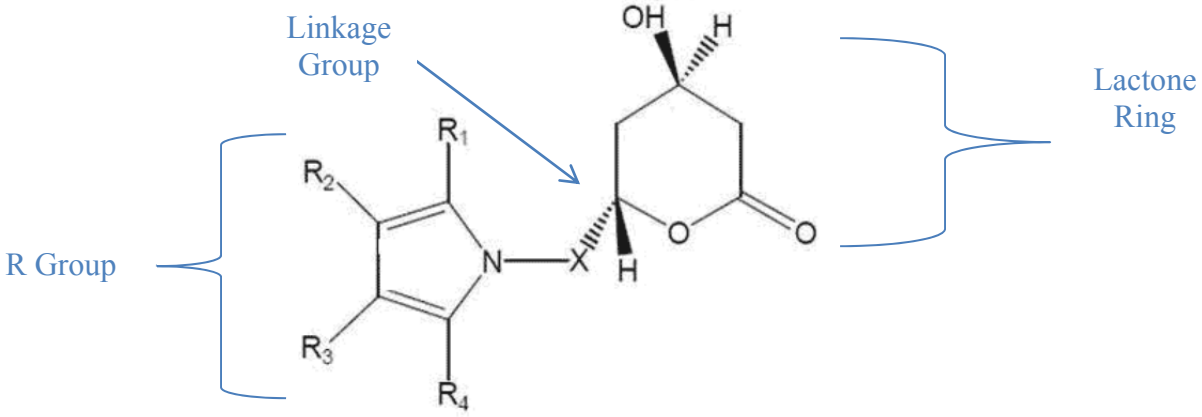
employer, Warner-Lambert. Warner Lambert patent attorneys, including Jerry F. Janssen, prosecuted the application.

60. This lawsuit alleges Warner Lambert intentionally and affirmatively lied to the PTO regarding the single most material facts that enabled it to procure the '995 patent as well as a later reissue of that patent. To understand that fraud, the circumstances behind the Original Lipitor Patent must be understood. This complaint therefore now describes the background, claims, and uses of the Original Lipitor Patent.

1. The Patent Specification Claims Atorvastatin, "the Corresponding Ring-Opened Acids Derived Therefrom" in Salt Form, and the R-trans and S-trans Enantiomers

61. Warner-Lambert stated in the patent specification for the Original Lipitor Patent that "in its broadest aspect the present invention provides compounds of structural formula I."

Figure 6: Warner-Lambert's Structural Formula I



62. Like other statins, structural formula I contains a lactone ring, a linkage group (X), and an R group.

63. Warner-Lambert claimed compounds of structural formula 1 were "useful as hypocholesterolemic or hypolipidemic agents by virtue of their ability to inhibit the biosynthesis of cholesterol through inhibition" of the HMG-CoA reductase enzyme. For support, the specification detailed the biological activity of three compounds compared to the prior art.

64. Research in the 1980s demonstrated that statin molecules with opened lactone rings were highly potent cholesterol synthesis inhibitors – often more potent than the closed lactone ring forms of the same molecules. Warner-Lambert claimed that the invention contemplated the hydroxyl acids, or structural formula I with an opened lactone ring:

> Also contemplated as falling within the scope of the present invention are the hydroxyl acids, and pharmaceutically acceptable salts thereof, derived from the opening of the lactone ring of the compounds of structural formula I above.

65. Importantly, *Warner-Lambert's patent application specifies and covers a compound in which the R-trans enantiomer is isolated:*

> The compounds of structural formula I above possess two asymmetric carbon centers, one at the 4-hydroxy position of the pyran-2-one ring, and the other at the 6-position of the pyran-2-one ring where the alkylpyrrole group is attached. This asymmetry gives rise to *four possible isomers*, two of which are the R-cis- and S-cis-isomers and the other two of which are the R-trans- and S-trans-isomers. This invention contemplates only the trans- form of the compounds formula I above. (Emphasis added).

66. It is noted that the patent coverage of the Original Lipitor Patent for atorvastatin calcium, i.e., a compound having the structural formula I which included versions in which the R-trans enantiomer is isolated, is not disputed by Warner-Lambert or Pfizer; again, this description provides the context for the later fraudulent actions of Warner-Lambert.

67. As the inventor of Lipitor testified, the compounds of the '893 application and Patent were not limited to any particular stereochemistry; "this one structure is meant to represent four different stereo isomers," the R-trans, S-trans, R-CIS, and S-CIS isomers[4] at atorvastatin acid (Roth Tr. at 231.)

[4] *Isomers* are two or more compounds with the same chemical formula but different arrangements of atoms.

2. The PTO Issues the Original Lipitor Patent

68. On July 21, 1987, the PTO issued the '893 Original Lipitor Patent. In the absence of an extension, the Original Lipitor Patent would have expired on May 30, 2006, twenty years from the date of the first application. Later extensions lengthened this period of patent protection until March 24, 2010. (The extensions are discussed later).

69. The '893 Patent envisaged the ability to have just the R-trans or S-trans enantiomers of compounds of structural formula I. The '893 Patent also recognized that these compounds could be in acid or salt form.

70. While the '893 Patent covered multiple formulations of structural formula 1, Warner-Lambert focused on developing and commercializing atorvastatin, the R-trans enantiomer of a particular compound with structural formula 1, in calcium salt form.

71. The '893 Patent thus covered atorvastatin calcium, the product that would be sold as Lipitor over the years.

D. The Fraudulently Obtained Follow-On Patent: Warner-Lambert Obtains the '995 Enantiomer Patent by Repeatedly Misrepresenting the R-trans Enantiomer's Activity

72. Although the '893 Patent would (and did) provide Warner-Lambert with many years of patent protection – and many years of exclusive sales of Lipitor – Warner-Lambert nevertheless sought to extend this monopoly by using any means, including fraud.

73. To do so, Warner-Lambert faced certain realities. For example, Warner-Lambert knew the PTO would reject an application to patent the enantiomer of the racemic mixture of atorvastatin because enantiomers of the chemical were already covered by the '893 Patent; an enantiomer "invention" would be either anticipated by the '893 Patent or obvious in light of the '893 Patent. Thus, the only way Warner-Lambert could get around this fundamental challenge in

procuring a follow-on enantiomer patent would be if it could convince the PTO that the isolated R-trans enantiomer had some claimed "surprising" or "unexpected" characteristic.

74. Senior management at Warner-Lambert instructed the Warner-Lambert researchers to review the existing biological data for the R-trans enantiomer to find data that supported a claim that the activity of the isolated R-trans enantiomer was surprising and, therefore, patentable.

75. During a meeting, Warner-Lambert senior management asked what the patent coverage was for the pure R-trans enantiomer. Roth responded that the R-trans enantiomer was covered under the '893 patent. Senior management then asked whether there was anything with the pure R-trans enantiomer that would make it patentable in and of itself. But Roth didn't know of any surprising characteristics that had unfolded over his years of working with the enantiomer atorvastatin. So Don Maxwell, the vice president of discovery research, assigned Roth the task of going back to existing lab books to see if there was some data that showed something surprising. Roth was instructed to provide any surprising data to Wyeth patent attorney Joan Thierstein.

76. Regarding the instructions from these senior Warner-Lambert officials, Roth has stated,

> if I found something surprising I would provide that. And what I did do was I provided that information to the patent attorney for Warner-Lambert and asked if that was sufficient, and it was and so that was the data that was used.

77. Of course, when senior Warner-Lambert management sent Roth back to the old laboratory notebooks to "find" something surprising, there was a wealth of knowledge about statins and the formulation of isolated R-trans enantiomers. The state-of-the-art about statin formulations gives context to Warner-Lambert's fraud.

1. The State of the Art: Knowledge of One Skilled in the Art of Statins in 1989

78. Statins are in the field of synthetic organic chemistry as it applies to discovery of compounds suitable for use as drugs directed to the regulation of the cholesterol biosynthetic pathway and HMG-CoA reductase inhibitors. One of ordinary skill in the art of statins would have at least a bachelor's degree in organic or medicinal chemistry; a general working knowledge of statins; several years of bench work in organic molecule synthesis; some general knowledge of biochemistry and enzymology; knowledge of stereochemistry of pharmaceutically active compounds; and knowledge of resolving racemates.

79. In 1989, one skilled in the art would be knowledgeable about the biological pathway for the synthesis of cholesterol, including that HMG-CoA reductase is the rate limiting enzyme in the biological pathway for cholesterol produced in an organism. One skilled in the art would also know that statins were potent inhibitors of HMG-CoA reductase and that the scientific literature had described *in vitro* assays as methods for testing a compounds' ability to inhibit cholesterol synthesis.

80. One skilled in the art would be aware that Mevastatin (compactin) is a natural HMG-CoA reductase inhibitor that exists as a single enantiomer. One would also be aware that Lovastatin (mevinolin), another potent inhibitor of HMG-CoA reductase, had been isolated and was structurally very similar to compactin. One would know that both Mevastatin and Lovastatin have lactones in the R-*trans* configuration.

81. One skilled in the art would also be aware that pravastatin (1979), symvastatin (1981), and fluvastatin (mid 1980's) were developed/isolated prior to 1989.

82. One skilled in the art would understand that pharmaceutical research into improved inhibitors of HMG-CoA was focused on analogues of known statins. One would be

aware that researchers were retaining the lactone ring while investigating substitutions on the remainder of the molecule.

83. One skilled in the art would know that the ring-opened form of the upper lactone portion of the previously discovered statins is significantly more active in inhibiting HMG-CoA reductase than the lactone (closed-ring) form.

84. One skilled in the art would be knowledgeable that HMG-CoA reductase inhibitors are enantiomeric and one enantiomer is likely to be more active than the other. One would know that the biological activity of a racemate in a biological system can be quite different from that of a single enantiomer, and one enantiomer is approximately twice as active as the racemate in terms of its operation in a target biological system (*i.e.*, one enantiomer is the "active" isomer, while the other is "inactive," and thus the active enantiomer is about twice as active as the racemic mixture). One would also know that it is desirable to separate and remove the less active enantiomer.

85. One skilled in the art would know that in the case of HMG-CoA reductase inhibitors, the R enantiomer was very likely to be the active enantiomer and, conversely, the S enantiomer was very likely to be inactive. One would know that these expected activities could be known with certainty by isolating and testing the activity of the enantiomers.

86. One skilled in the art would understand that racemic mixtures can be separated or resolved into the individual enantiomers by well-known methods of separation or resolution. Similarly, one would be aware that single enantiomers can be isolated by chiral or achiral synthesis.

87. One skilled in the art would be knowledgeable that it was common practice among medicinal chemists and others working in the drug discovery field in 1989 to use a single

structural formula to represent both enantiomer individually as well as mixtures of enantiomers. One would be similarly aware that whether a diagram depicting the structural form for a molecule or class of molecules shows a particular stereochemistry configuration (whether absolute or relative) depends on the context in which the diagram appears. One would know that if a diagram of a single enantiomer was intended to depict a racemate, to the exclusion of the enantiomer, it was possible to add an additional descriptor, such as (+/-), RS, or ('rac'), which would make it clear that the structure represented only a racemate.

88. One skilled in the art, given the '893 Original Lipitor Patent, would have known that compounds in the structural formula I were racemic, that there were a discreet number of enantiomers possible from the structural formula, and that there were known methods for dissolving the racemic mixture into the enantiomers.

2. The Application: Warner-Lambert Fraudulently Claims the R-Trans Enantiomer is Ten Times More Active than the Racemate

89. On July 21, 1989 – two years to the day after the '893 patent issued – Warner-Lambert and Roth applied for a patent for the R-trans enantiomer, *i.e.*, for the R-trans form of the ring-opened acid described in the '893 Patent: [R-(R*R*)]-2-(4-fluorophenyl)-β,δ-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[phenylamino)carbonyl]-1H-pyrrole-1-heptanoic acid and "its lactone form and salts thereof." (U.S. Patent Application No. 384187). This application would eventually lead (albeit by fraud) to the issuance of the '995 Enantiomer Patent.

90. Roth was the inventor and applicant; as part of the application, Roth provided a declaration acknowledging his duty to disclose information material to the examination of the application to the PTO, pursuant to 37 CFR 1.56 -1.63. Roth appointed Warner-Lambert's patent attorneys as his attorneys/agents and authorized them to prosecute the application. He further directed that all correspondence related to the patent application be sent to Warner-

Lambert attorney Joan Thierstein. The application itself was signed and submitted by a Warner-Lambert employee, Elizabeth M. Anderson.

91. Warner-Lambert, including Thierstein, Anderson, and Roth, prosecuted the application from 1989 to 1993.

92. In the application, Roth and Thierstein claimed, "[i]t is now *unexpectedly found* that the enantiomer having the R form of [a] ring-opened acid [described in the '893 Patent] … *provides surprising inhibition* of the biosynthesis of cholesterol." Roth and Thierstein further claimed "an ordinarily skilled artisan may not predict the *unexpected and surprising inhibition* of cholesterol biosynthesis of the present invention in view of [prior] disclosures." In support of this contention, Warner-Lambert presented only one piece of evidence: a short table stating that Warner-Lambert's Cholesterol Synthesis Inhibition ("CSI") assay data demonstrates the R-trans enantiomer is *one hundred-times more active* than the S-trans enantiomer, and *ten-times more active* than the racemate, in inhibiting the synthesis of cholesterol *in vitro* ("CSI Table"):

Figure 7: Specification CSI Table

is now also incorporated by reference therefor. The CSI data of the compound I, its enantiomer the compound II and the racemate of these two compounds are as follows:

Compound	IC_{50} (micromoles/liter)
[R-(R*R*)] isomer	0.0044
[S-(R*R*)] isomer	0.44
Racemate	0.045

Accordingly, the present invention is the pharmaceutical composition prepared from the compound of the formula I or II or pharmaceutically acceptable salts thereof.

93. Warner-Lambert claims the "present invention" – the R-trans enantiomer – based on the data presented in the CSI table.

94. The CSI assay measures the ability of a compound to inhibit cholesterol biosynthesis along the entire cholesterol biosynthesis pathway and is one of the most commonly used methods to test a compound's ability to inhibit the synthesis of cholesterol *in vitro*. The results of a CSI assay are reported as an IC_{50} value, the concentration of a test compound that produces 50% inhibition in the conversion of cholesterol-[^{14}C] acetate to radioactive cholesterol. The CSI test does not identify the specific step in the cholesterol biosynthetic pathway that is being inhibited, nor is it specific to HMG-CoA reductase.

95. Two other commonly used methods of measuring a compound's inhibition of cholesterol are the *in vivo* Acute Inhibition of Cholesterol Synthesis ("AICS") assay and the *in vitro* CoA Reductase Inhibition ("COR") assay. The COR assay measures a compound's ability to inhibit HMG-CoA reductase specifically and is typically used to confirm that the activity seen in the CSI assay is attributable to inhibition of the desired target: HMG-CoA reductase.

96. One skilled in the art of statins in 1989 – and indeed one skilled in the art even today -- would have expected the active R-trans enantiomer to be about twice as active as the racemate in inhibiting cholesterol synthesis. After all, the racemic mixture is simply the active enantiomer evenly combined with the inactive enantiomer (and thus equal amounts of each yield an active enantiomer that is twice as active as the mixture). If the activity of one enantiomer is truly *ten times* that of the racemate, that indeed would be "unexpected" and "surprising"; in fact, it would be an extroadinary development in the science of stereochemistry! But the truth is that this was a lie.

a. The CSI Table Is Misleading and Affirmatively False

97. Warner-Lambert's biological data – the CSI Table – was both affirmatively false and intentionally presented in a misleading manner. The CSI Table purports to present reliable scientific data. It does not. In truth, it contains limited data cherry-picked from multiple flawed

tests conducted over several years using different formulations of various atorvastatin salts. The reliable data actually shows that the R-trans enantiomer is, as expected, only about two times more active than the racemic mixture – far from the "surprising" tenfold increase Warner-Lambert claimed.

(1) The CSI Table is Misleading

98. Warner Lambert's CSI Table is misleading because it purports to present reliable and confirmed data, but does not. The CSI Table does not disclose the source of its data and fails to indicate the number of CSI assays performed, the degree of variation in the test results, what molecules were tested, the time period over which the assays were run, or whether the results presented were drawn from multiple tests. Given this lack of specification, a skilled addressee would conclude the data had been confirmed by a number of repeat assays and fairly depicted all relevant appropriate data.

99. Warner-Lambert ran at least a number of CSI assays prior to applying for the '893 Patent – over a multi-year period and on various salt formations – as it tested the R-trans enantiomer of structural formula I. The results fluctuated wildly. While not apparent from the face of the specification, Warner-Lambert claimed in subsequent litigation that the CSI Table was created by averaging the results of all of the available CSI screens. This was not true. Warner-Lambert cherry-picked from among the results -- not from all the results -- in order to generate a table that supported the claim of "surprising activity."

100. For example, the CSI Table combines results from a number of different CSI assays and compares them to a separate CSI assay. But the standard in the 1980s for giving numbers of the kinds found in the CSI Table was to conduct repeated head-to-head tests; Roth himself has repeated acknowledged that head-to-head testing provides the best way to compare quantitative differences in activity. However, the data presented to the PTO for the R-trans

enantiomer and S-trans enantiomer were taken from a single run of the same experiment: CSI 120. And in bizarre contrast, the data collected for racemate represents an "average" of five separate assays: CSI 92, CSI 93, CSI 95, CSI 102, and one of three recorded values from CSI 118.

Figure 8: Sources for Specification CSI Table

Compound	IC 50 (micromoles/liter)
R-trans Enantiomer	.0044
S-trans Enantiomer	.44
Racemate	.045

Source	Original Form	IC 50 (micromoles/liter)
CSI 120	Sodium Salt	.00444
CSI 120	Sodium Salt	.44
CSI 92	Lactone	.0346
CSI 93	Lactone	.0275
CSI 95	Lactone	.0631
CSI 102	Lactone	.0912
CSI 118	Sodium Salt	.0097

101. Second, taking an average across different days and experiments is not appropriate. The five "averaged" assays were conducted over a three-year period from July 1985 through October 1988. When taken as a whole, the results of these five experiments reported for the racemate are so variable that they cannot be averaged together with any reliability and does not provide a scientifically meaningful result.

102. Third, it is also inconsistent with accepted pharmaco-chemistry to "average" the results of CSI values derived from both opened lactones and separately synthesized sodium salts.

Four of the assays reflected in the racemate data in the CSI Table (CSI 92, 93, 105, 102) started with the lactone (unopened) form of racemic atorvastatin and were treated with sodium hydroxide to open the lactone ring and create a sodium salt in the process of running the test. One of the assays (CSI 118) started with chemically synthesized sodium salt of racemic atorvastatin prepared by a medicinal chemist.

103. One skilled in the art would be aware that if lactone rings do not fully open when exposed to sodium hydroxide, the presence of inactive material will result in a higher IC 50 value – indicating the compound is less active than it actually is. One skilled in the art would also expect that the IC 50 values for the racemic lactones in each of the four CSI assays would be similar, not report a threefold difference – from .02 (CSI 93) to .09 (CSI 102); One skilled in the art would also expect the IC 50 values for the racemic lactones to be similar to the value of the racemic sodium salt, not report a tenfold difference – from .009 (CSI 118) to .09 (CSI 120). Such disparate values suggest not all of the lactone rings opened during the test and/or other solubility issues that compromise the accuracy of the data.

104. Notwithstanding that accepted science rejects the use of the average value, the table does not even constitute a true average. Though available, Warner-Lambert did not include all results from all conducted CSI assays, omitting the results from at least nine other CSI tests, including CSI 107, CSI 111, CSI 112, CSI 119, CSI 122, CSI 123, CSI 124, CSI 136, and CSI 138.

Figure 9: CSI Data (IC 50 in micromoles/liter)

CSI#	Date	Racemic Lactone	R-trans Lactone	S-trans Lactone	Racemic Sodium Salt	R-trans Sodium Salt	S-trans Sodium Salt	Racemic Calcium Salt	R-trans Calcium Salt	S-Trans Calcium Salt
92	7/24/85	.0346								
93	8/27/85	.0275								
95	10/15/85	.0631								
102	1/15/87	.0912								
107	7/20/87		.0355	.631						
111	2/25/88							.0024		
112	3/28/88							.0776		
118*	10/24/88				.00977			.257	.0251	> 1.0
					.00913			.234	.0216	
119	11/15/88							.00324		
120	2/2/89					.00498	.444			
122	4/21/89					.00313				
123	5/31/89								.00948	
124	6/12/89				.001					
136	7/31/91					.0322				
138	1/31/95					.0169				

* = test calculated multiple values using different methods.

Blue = Roth used in CSI table

Yellow = Roth reported in the Roth Declaration (discussed *infra*)

105. Depending on which assays were included or excluded, the CSI Table could have, and would have, reported very different results. For example, Roth has acknowledged that had the results of CSI 107 been included in his "average," there would be no surprising or unexpected result. Rather, had CSI 107 been included, the CSI Table show only the expected

twofold increase in the activity of the R-trans enantiomer compared to the racemate. Roth has claimed he did not include CSI 107 because he believed that the compounds it tested were not enantiomerically pure; yet, he included the results of CSI 120, which suffered from similar level of contamination.

106. Similarly, the CSI Table would have shown only this expected twofold increase had Warner-Lambert excluded the results of CSI 118 from the "average." As discussed below, CSI 118 suffered from myriad problems.

107. No matter how Warner Lambert, Thierstein and/or Roth rigged the numbers, the fact is that the R-trans enantiomer is only twice as active as the racemate.

(2) The CSI Table is Affirmatively False

108. Warner-Lambert's claim that the R-trans enantiomer has surprising activity is false. Warner-Lambert's claim that the R-trans enantiomer is ten times more active than the racemate is false. Warner-Lambert, including Roth, knew the R-trans enantiomer is, as would be expected by one skilled in the art, only about twice as active as the racemic mixture.

109. Warner-Lambert, including Thierstein and Roth, did not tell the PTO that it possessed data that expressly contradicted representations in its patent specifications.

110. In addition to CSI assays, Warner-Lambert assessed the activity of the R-trans enantiomer, S-trans enantiomer, and the racemate through the *in vivo* AICS assay. The ACIS assay – the only screen to be conducted twice and with consistent results – showed a twofold increase in activity of the R-trans enantiomer over then racemate. But Warner-Lambert never submitted the ACIS data to the PTO.

111. Warner-Lambert also assessed the activity of the R-trans enantiomer, S-trans enantiomer, and the racemate through the *in vivo* COR assay. The COR data was consisted with

a twofold increase in activity of the R-trans enantiomer over then racemate. But Warner-Lambert never submitted the COR data to the PTO.

112. Warner-Lambert's own research reports conclude that the R-trans enantiomer was approximately twice as active as the racemate. A May 31, 1989 report signed by Dr. Sliskovic states that the R-trans enantiomer "was approximately *twofold* more active at inhibiting cholesterol synthesis acutely *in vivo* compared to the racemic mixture …. *This is to be expected* if 50% of the racemic salt is the inactive isomer." A June 1, 1989 report signed by Roth also reported a twofold increase in activity of the active enantiomer over the racemate: "[a]s expected, [the R-trans calcium salt] was twofold more potent than … the racemic calcium salt, which contains 50% inactive isomer." Other internal memoranda from September and December 1989 similarly conclude that, as expected, the R-trans enantiomer was twice as active as the racemate. But Warner-Lambert never shared its own conclusion with the PTO.

113. Roth and Warner-Lambert knew that a person skilled in the art would read the CSI Table as appropriately reflecting (1) all of the appropriate CSI data available to Warner-Lambert for the relevant compounds, and (2) the data as a whole provided reasonable grounds for the findings set forth in the CSI Table. Roth, Theirstein, and Warner-Lambert intended that the CSI Table be read as demonstrating a tenfold increase in activity and, therefore, supporting patentability.

114. Roth, Theirstein, and Warner-Lambert also knew that the CSI data did *not* provide any "surprising" results. After all, Warner-Lambert scientists, including Roth, had conducted the various CSI assays over a period of more than three years. Certainly, if the assays had disclosed anything surprising -- certainly something as shocking as a ten-fold increase in biological activity -- that would have been learned, in real time, as the tests unfolded. But none of Warner

Lamberts' internal documents (produced to date in related litigation) or any of the literature published by Dr. Roth and his team concerning the discovery of atorvastatin refer to, or even suggest, a ten-fold increase in activity.[5]

115. Instead, it was only after senior Warner-Lambert managers (not the scientists) instructed Roth to go back and "find" something in the data, and after a hodge-podge analysis of different tests on different compounds was cobbled together, that the claimed ten-fold biological activity materialized. If Warner-Lambert truly had CSI data that established the R-trans enantiomer was ten times more active than the racemate, as claimed in the '995 patent specification, one would expect to fund some commentary or explanation as to the different outcomes of the CSI and AICS testing. But no such commentary is contained in the documents produced by Warner-Lambert to date in related patent litigation.[6]

116. Furthermore, accepted chemistry in 1989 counseled to conduct to controlled tests of the proposed hypothesis, *i.e.*, that there were some "surprising" attributes of the isolated R-trans enantiomer over the racemic mixture. This would have entailed Warner-Lambert conducting *new* tests in response to senior managements' demand to find something surprising. Instead, the entire direction, dictated by senior Warner-Lambert management, was *not* to conduct acceptable science in order to make fair and accurate representations to the PTO. The instructions were simply to go back and gin-up old data to give an impression, albeit false, of some type of "surprising" attribute.

[5] *See Ranbaxy Australia Pty Ltd. v. Warner-Lambert Company LLC*, 2006 FCA 1787 (December 20, 2006).

[6] *See Ranbaxy Australia Pty Ltd. v. Warner-Lambert Company LLC*, 2006 FCA 1787 (December 20, 2006).

3. The Initial Rejection: The PTO Determines the Claimed Compounds Are Anticipated By the '893 Patent

117. On March 22, 1990, pursuant to 35 U.S.C. 102(b), the PTO rejected all claims in the initial application as anticipated by -- that is covered by -- the Original '893 Patent. The PTO determined that the '893 Patent "restrict[ed] the invention to the trans-isomers and… specif[ied] the R*, R* configuration. Thus, the claimed compounds, salts, compositions, and method are considered to be anticipated by [the '893 Patent]." Put simply, the PTO rejected Warner-Lambert's enantiomer patent application because the invention was already covered by the claims in the Original Lipitor Patent.

118. The concepts of "anticipation" and "non-obviousness" are distinct but related concepts under patent law. A proposed invention may be rejected under 35 U.S.C. §102 (b) as being anticipated, that is, already covered by, a previous patent. Alternatively, even if a proposed invention is not identically disclosed or described as set for in §102, under 35 U.S.C. §103 a patent may not issue for obviousness "if the differences between the subject matters sought to be patented and the prior art such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains . . . " Because the patent examiner had concluded that the Original Lipitor Patent anticipated, that is already covered, the isolated R-trans enantiomer form of atorvastatin, the examiner did not need to reach the concept of obviousness.

119. In response to this rejection, Warner-Lambert argued against anticipation on technical grounds that the '995 application addressed specific enantiomers, and the '893 addressed only racemates, "the presently claimed compounds are for individual enantiomers and therefore differ from the teaching in [the '893 Patent] only to mixtures of enantiomers."

120. Warner-Lambert, through Thierstein, argued that the '893 Patent did not specifically identify, and therefore did not technically "anticipate," the R-trans enantiomer:

> In molecules of the kind disclosed in [the '893 Patent], each possible isomer also exists in two forms which depend on a configuration which is expressed in absolute terms relative to the remainder of the molecule. The forms are denoted as an R form and an S form. These two forms are recognized by an ordinarily skilled artisan to be enantiomeric forms each having a specific chirality. In [the '893 Patent] the disclosure is not limited to compounds having such a specific chirality. Thus, each isomer of [the '893 Patent] is a mixture of enantiomers and not the currently claimed individual enantiomers having an R chirality.

In later patent litigation, Roth himself disagreed with, and outright rejected, this argument.

121. The PTO examiner also, again rejected Warner-Lambert's argument that the Original Lipitor Patent did not anticipate the R-trans enantiomer. On November 7, 1990, the examiner issued a final rejection on anticipation grounds. The examiner determined that the '893 Patent described the R-trans enantiomer:

> Applicant's arguments… have been carefully considered, but such are not persuasive. Where a reference discloses a genus or compound of similar structure which are sufficiently limited in number, the reference is deemed to provide description of those compounds just as specifically as if they were identified by name.

The examiner observed that to isolate the claimed invention, the R-enantiomer from the compounds disclosed in the '893 Patent, "one merely has to select from the limited possibility of isomers to arrive at the claimed invention, and separate them using conventional techniques." Following the rejection, Warner-Lambert abandoned the application.

4. The Renewed Application: Warner-Lambert Submits the Roth Declaration, Again Falsely Claiming the R-Trans Enantiomer is Ten Times More Active than the Racemate

122. On February 29, 1991, Warner-Lambert revived its application and filed a preliminary amendment, signed by Thierstein.[7] The amendment included a declaration by inventor Roth ("Roth Declaration"). The Roth Declaration was submitted in order to overcome an obviousness rejection and support patentability of the R-trans enantiomer. In the declaration, Roth again acknowledges his duty to be truthful.

123. The Roth declaration again claims a "surprising" and "unexpected" tenfold increase in activity. It (falsely) professes to present seemingly objective evidence of an unexpected characteristic of the isolated R-trans enantiomer. Warner-Lambert, through Thierstein and Roth, claimed this characteristic would allow issuance of an R-trans enantiomer patent despite the claimed invention being *prima facie* obvious in light of the Original Lipitor Patent. The Roth Declaration simply presented more of the same: misleading and affirmatively false biological data.

a. Warner-Lambert Admits the R-Trans Enantiomer Is *Prima Facie* Obvious

124. While continuing to argue that the proposed R-trans enantiomer patent was not technically anticipated by the Original Lipitor Patent, Warner-Lambert also raised, on its own, the issue of obviousness. Indeed, Warner-Lambert admitted that the R-trans enantiomer was *prima facie* obvious in light of the '893 Patent.

125. In its remarks in support of the renewed patent application, Warner-Lambert directs the examiners' attention to a decision of the U.S. Court of Customs and Patent Appeals,

[7] The patent specification accompanying the renewed application also contains a chart (the "CSI Chart") showing ten times greater activity of the R-trans enantiomer than the corresponding racemate. The information contained in this chart is identical to that presented in the original application. See section ____.

In re May and Eddy, 197 USPQ 601, 607 (1978), quoting: "[a]s recognized in *In re Williams*, 36 CCPA 756, 171 F.2d 319, 80 USPQ 150 (1948), the novelty of an optical isomer is not negated by the prior art disclosure of its racemate."[8] "Clearly," Warner-Lambert asserts, "this case law is applicable here."

126. In *May*, the *applicant conceded prima facie obviousness*, but submitted "rebuttal evidence" in the form of four declarations that it was "unexpected" that the compounds in question did not exhibit the addictive qualities of most opiates. The PTO refused to consider the rebuttal evidence. The U.S. Court of Customs and Patent Appeals reversed. "[B]alancing the *prima facie* case of obviousness made out by the PTO against appellants' objective evidence of nonobviousness," the Court concluded, "the subject matter of claims 11-13 would not have been obvious to one of ordinary skill in the art." According to *May*, an applicant may provide declarations identifying objective evidence of a surprising characteristic to overcome *prima facie* obviousness.

127. Warner-Lambert purported to do just that. In the remarks, Warner-Lambert states,

> Following the Williams case Applicant also now provides by a declaration a comparison among each enantiomer and mixture of enantiomers. This comparison is provided to overcome the Roth reference [that is, the reference in the '893 Patent] of the present rejection to facilitate a finding of patentability and moving the prosecution toward resolution of pertinent issues. In other words, *although Examiner has not included a rejection under 35 U.S.C. 103 [for obviousness] Applicants are including a rebuttal of such rejection to comply with the Williams case law.*

[8] The facts here are quite distinct from Williams. In Williams, as here, the applicant sought a patent on a particular enantiomer. The Williams court determined that the racemic compound had been disclosed in the prior art, but (in contrast to this situation) the fact that the compound was racemic had not been previously disclosed.

Warner-Lambert further describes the declaration as "provid[ing] the data as set out in the present application in a manner to provide patentability to the application,"[9] and states, "in other words, *the declaration is submitted to provide evidence of patentability* to the instant invention."

b. The Roth Declaration is Misleading and Affirmatively False

128. Warner-Lambert submitted the Roth Declaration in an effort to overcome the otherwise inevitable rejection on obviousness grounds. The Roth Declaration states "the antihypercholesterolemia properties of ["R-enantiomer," or "Compound I"] and ["S-enantiomer," or "Compound II"] and mixtures thereof are assessed using essentially the CSI screen that is disclosed in [the '893 Patent]." The declaration continues, claiming that the R-trans enantiomer has "activity greater than *fifty-fold more* than that of Compound II and which indicates activity *at least ten-fold more* than that of the racemate," and contains the following table:

8. THAT, in said assessment, the datum from the Compound I, the datum from its enantiomer the Compound II and the datum from the racemate of the two compounds I and II are as follows:

	Compound	IC_{50} (micromoles/liter)
I	[R-(R*R*)] isomer	0.025
II	[S-(R*R*)] isomer	>1.00
	Racemate	0.26

9. THAT, the data demonstrate that the Compound I provides an IC_{50} which indicates activity greater than fifty-fold more than that of Compound II and which indicates activity at least ten-fold more than that of the racemate;

129. The Roth Declaration states that the available "the datum from the compound I" (the R-trans enantiomer) and "the datum from the racemate" (the S-trans enantiomer) are presented below, implying (at minimum) that the values given reflect all appropriate, reasonably

[9] Warner-Lambert thus at least tacitly acknowledges that the CSI Table previously submitted in the patent specification is not sufficient to provide patentability.

available CSI assay data. The declaration further claims that "the differences in the data … among Compounds I, II and racemate shows the activity of Compound I is *surprising and unexpected* because if the Compound II is accepted as inactive, the activity of the Compound I would be expected to be only twice that of the racemic mixture."[10]

130. The Roth Declaration, like the CSI Table, purports to present reliable scientific data but does not disclose the source of that data. Given this lack of specification, a skilled addressee would conclude that Warner-Lambert would not have included the CSI Table in the specification in such an unqualified way unless the data had been confirmed by a number of repeat assays.

131. In fact, the Roth Declaration presents unreliable data from a single, deeply flawed screen – CSI 118. The declaration is false and misleading.

Figure 10: Sources for Roth Declaration Table (IC 50 in micromoles/liter)

CSI#	Date	Racemic Lactone	R-trans Lactone	S-trans Lactone	Racemic Sodium Salt	R-trans Sodium Salt	S-trans Sodium Salt	Racemic Calcium Salt	R-trans Calcium Salt	S-Trans Calcium Salt
118*	10/24/88				.00977			.257	.0251	> 1.0
					.00913			.234	.0216	

* = test calculated multiple values using different methods.

Blue = Roth used in CSI table (discussed *supra*)

Yellow = Roth reported in the Roth Declaration

132. In addition to generating a value for the racemic sodium salt Roth used in the CSI chart in the patent specification, CSI 118 compared all three forms of calcium salt (R-trans, S-

[10] Roth's declaration concludes with a paragraph stating, in part, "these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both… and that such willful false statements may jeopardize the validity of the above identified US patent application… or any patent issuing thereon."

trans, and racemate) in a single head-to-head assay. The screen was never re-run to confirm the reported results.[11] The test results are unusable for a number of reasons.

133. First, in order to obtain accurate IC_{50} values, the concentration of the test solutions must be known prior to testing; but Warner-Lambert did not determine the concentration of its test solutions prior to conducting the CSI 118 test. Without accurate information about the concentration of the solutions used in the CSI 118 test, the IC_{50} values obtained in CSI 118 cannot be used to demonstrate a tenfold increase in activity of the R-trans enantiomer over the racemate.

134. Second, Warner-Lambert's own lab books show that the compounds in CSI 118 did not dissolve completely in the stock solution. Using non-homogeneous suspensions can result in variations in the concentrations of the compound in the assay solution leading to wide variation in the results obtained. Given this limitation, the most that the CSI 118 results can be said to determine is whether a compound has *any* activity, not whether a compound has a twofold, threefold, or tenfold increase in activity over another compound.

135. Third, an acceptable CSI test should record similar results for the racemic sodium salt and the racemic calcium salt. Roth has agreed that, in general, the results for the racemic sodium salt and the racemic calcium salt should be equivalent or similar. Yet, in CSI 118, the results of the racemic sodium salt (.00977) and racemic calcium salt (.257) are vastly different, almost a twenty-five-fold difference. The difference was so great that the IC_{50} value for the R-trans enantiomer calcium salt showed far less potency than the racemic sodium salt – that is, the R-trans enantiomer, *the active enantiomer,* of the calcium salt was *less active* than the racemate

[11] Roth has admitted that he did not conduct any additional tests to confirm that the biological data presented in the patent was in fact correct: "it is true that [the biological data that was included in the patent] went out without any subsequent tests being asked for by me to repeat that data."

of the sodium salt. This difference should have been a red flag that something was wrong with the screen, likely a problem related to solubility issues.

136. Finally, the claim in the Roth Declaration of ten times activity is also affirmatively false because the activity of the isolated R-trans enantiomer is not in fact ten times greater than the racemate. Had Warner-Lambert employed an acceptable scientific testing process, the data would have revealed the R-trans enantiomer had at best a twofold advantage over the racemate.

137. Roth and Warner-Lambert were aware of the numerous problems with CSI 118 identified above and knew that the results of CSI 118 were not scientifically sound. Yet, in the face of radically different values for the sodium and calcium salts, solubility problems, unknown solution concentrations, and results that showed the racemate of one salt was more potent than the R-trans enantiomer of another salt, they used this questionable and unreliable data to support the false claim that the isolated R-trans enantiomer has ten times greater inhibition of cholesterol synthesis than the racemate, and specifically claimed this as "a surprising level of activity" which, in turn, supported patentability. Warner-Lambert and Roth admit this: Dr. Roth has admitted under oath that he submitted CSI data for the purpose of demonstrating "a surprising level of activity" which therefore supported patentability:

> Q. So [the biological data] was put in to demonstrate this surprising level of activity for the purpose of obtaining a patent, was it not?
>
> A. [Dr. Roth:] Yes, I guess you would say that that would be true. I mean, the data supported a surprising level of activity, which we thought would be novel and surprising and therefore would support patentability.

138. Warner-Lambert knew that a person skilled in the art would read the Roth Declaration as fairly reflecting all of the appropriate CSI data available to Defendants for the

relevant compounds, and that the data as a whole provided reasonable grounds for the findings set forth in the Roth Declaration. Roth and Warner-Lambert intended that the Roth Declaration should be read as suggesting a tenfold increase in activity and therefore supporting patentability.

5. The Final Rejection: The PTO Determines the R-Trans Enantiomer is Anticipated

139. On September 16, 1991, the PTO examiner issued a final rejection of the follow-on patent application, rejecting all claims under 35 U.S.C. 102(b) as being anticipated by the '893 Patent for the reasons set forth in the two rejections issued in 1990.

6. The Appeal: the PTO Determines the R-Trans Enantiomer is Prima Facie Obvious.

140. On January 15, 1992, Warner-Lambert appealed the examiner's rejection to the Board of Appeals, claiming "[t]he R isomer as claimed appears to be at least *100 times more active than its corresponding S isomer and more than 10 times more active than the mixture.* Under ordinary circumstances one would have expected only a two-fold difference between the particular R isomer and the mixture." The appeal was signed by Attorney Ronald A. Daignault, a Warner Lambert employee. Daignault states, "the present invention describes the particular R isomer which is found to have *greater than 10 times the activity* of the compound described in the prior art reference, namely, the racemic mixture," "the compound of the present invention… does not produce substantially the same result since it has *greater than 10 times the activity* than the reference compound," and "the R isomer is the most desired and the most *surprisingly active* isomer of the two possibilities if one is to select from the trans compounds…."

141. Acknowledging that the isolated R-trans enantiomer is *prima facie* obvious over the '893 Original Lipitor Patent, Warner-Lambert argued that the obviousness is overcome by the surprising and unexpected activity claimed in the Roth Declaration: "The examiner's rejection is erroneous as a matter of law by applying the facts of the present case to the wrong

law. The issue here is whether an optical isomer is novel over its prior disclosed racemic mixture. The law as state[d] in May and Eddy affirming In re Williams says yes."

142. On March 24, 1992, the examiner filed an answer to Warner-Lambert's appeal. The examiner alleged no new grounds for denial of the application, but reiterated the previously disclosed grounds, stating, "even if a preferred isomer were not disclosed [by the '893 Patent], one skilled in the art expects one of the individual isomers to be more active than the other since this, too, is knowledge contemporary in the art."

143. On October 19, 1992, the Board of Appeals overturned the Examiner's rejection *for anticipation* of the application, concluding that the '893 Patent did not technically anticipate the R-trans enantiomer:

> at best, only describes the trans racemate containing the R-trans and the S-trans isomers in admixture. Nowhere does [the '893 Patent] state or suggest which optical isomer is preferred and, moreover, does not specifically mention how one skilled in the art could make the pure optical isomer separately. In view of the above, we are unable to subscribe to the examiner's contention that the ['893 Patent] anticipates the claimed subject matter.

144. However, the Board recommended to the examiner that upon remand the patent should be rejected on the basis of *obviousness:*

> Upon further prosecution of this application before the examiner, we recommend that the examiner analyze the claimed subject matter under the provisions of §103 of 35 USC. *An obviousness rejection of claims directed to an optically pure isomer appears to be in order when, as here, (1) the product of the prior art is known to be racemic and (2) where methods for resolving the racemic mixture into the pure optically active isomers are known to those skill[ed] in the art.*

7. The '995 Patent Issues: PTO Relies on Biological Data to Overcome Obviousness

145. On March 16, 1993, apparently without any further formal proceedings or briefing, the PTO issued a Notice of Allowability for the follow-on, isolated R-trans enantiomer

patent application. U.S. Patent Number 5,273,995 (the "'995 Enantiomer Patent" or the "'995 Patent") issued on December 28, 1993.

146. Warner-Lambert had presented the results of CSI screens in both the '995 Patent specification and the Roth Declaration to support the contention that the R-trans enantiomer is surprisingly and unexpectedly *ten times more active than the racemate* and therefore not obvious in light of the '893 Patent. Warner-Lambert made this representation in the original application, the Roth Declaration, the appeal to the PTO, and in the final patent specification. This is the only "surprising" activity of the isolated R-trans enantiomer that is ever discussed in the '995 Patent application, and therefore, the sole reason Warner-Lambert was able to overcome an obviousness rejection.

147. The PTO relied on the Roth Declaration and the CSI Table to find that the R-trans enantiomer was not obvious in light of the '893 Patent. The Board of Appeals explicitly (i) directed the examiner to re-evaluate the application for obviousness, and (ii) stated that an obviousness rejection appeared to be appropriate. The examiner did precisely that. The examiner relied on Warner-Lambert's claim of "surprising" and "unexpected" activity and determined that the charts presented in support of that claim (both in the patent specification itself and the Roth Declaration) were sufficient to overcome a rejection on obviousness grounds. The only "surprising" or "unexpected" characteristic of the isolated R-trans enantiomer Warner-Lambert claimed was the tenfold increase in activity compared to the racemic mixture. The only data presented in support of those claims were contained in the patent specification (the CSI Table) and Roth Declaration.

148. The inclusion of particular language and data in the patent specification itself confirms that the PTO relied on both the claim of surprising and unexpected activity and the data

submitted in support of that claim. The specification states, "[i]t is now unexpectedly found that the enantiomer having the R form of [a] ring-opened acid [described in the '893 Patent], …that is [R-(R*R*)]-2-(4-fluorophenyl)-β,δ-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[phenylamino)carbonyl]-1H-pyrrole-1-heptanoic acid, provides surprising inhibition of the biosynthesis of cholesterol." The specification further states "an ordinarily skilled artisan may not predict the unexpected and surprising inhibition of cholesterol biosynthesis of the present invention in view of [prior] disclosures."

149. But for Warner-Lambert's fraud, the '995 Enantiomer Patent would never have issued.

E. Warner-Lambert Intended to Deceive the PTO

150. Warner-Lambert's false claims and data were made with the specific intent that the PTO rely on those claims in order to issue a follow-on patent, and with knowledge they were false and misleading. Roth and Warner-Lambert knew that a person skilled in the art would read the CSI table and the Roth Declaration as a representation that the results in the table fairly reflected all of the scientifically reliable CSI data available to Defendants for the relevant compounds, and that the data as a whole provided reasonable grounds for the findings set forth in the CSI Table. Roth and Warner-Lambert intended that the CSI table and the Roth Declaration should be read as suggesting a ten-fold increase in activity and therefore supporting patentability.

1. Warner-Lambert Manipulated the Existing Biological Data to Show a Ten Fold Increase in Activity and Defendants Intentionally Presented False Information

151. Warner-Lambert manipulated the existing biologic data in order to show a ten-fold increase in activity.

152. Warner-Lambert has acknowledged that head-to-head testing provides the best way to compare quantitative differences in activity, yet it did not present such head-to-head data

in support of his claim of ten-fold activity of the R-isomer over then racemate. Instead, Warner-Lambert selected results from various tests conducted on different days, using different salts, and suffering from various flaws and presented these cooked-up results in the CSI Table included in the patent specification. Such a gross departure from accepted chemistry practice shows knowledge of falsity.

153. Warner-Lambert acknowledged that had the results of CSI 107 been included in his "average," there would be no surprising or unexpected result. Warner-Lambert has claimed it did not include CSI 107 because it believed that the compounds it tested were not enantiomerically pure; yet, it included the results of CSI 120, which suffered from a not substantially different level of contamination. Such a gross departure from accepted chemistry practice shows knowledge of falsity.

154. Warner-Lambert claimed that it did not provide the data from CSI 119 to the PTO because CSI 119 was not a head-to-head comparison, and it claimed it believed that it was inappropriate to compare individual data points from different experiments. Yet, Warner-Lambert used different data points from multiple experiments to generate the data contained in the CSI Table. Such a gross departure from accepted chemistry practice shows knowledge of falsity.

155. Warner-Lambert included one of the three results from CSI 118 in the CSI Table in order to show an alleged ten-fold increase in activity. The sodium salt prepared by opening the racemic lactone in CSI 92, 93, 95, and 102 should have given substantially identical, or at least very similar, values to the racemic sodium salt that was separately prepared in CSI 118. Yet, the results for the racemic sodium salt in CSI 118 differs from the results of the four lactone

CSI tests by a factor of ten. Such a gross departure from accepted chemistry practice shows knowledge of falsity.

156. In CSI 118, the results of the racemic sodium salt and racemic calcium salt are vastly different, showing as much as a twenty-five-fold difference. The difference was so great, that the IC_{50} value for the R-trans enantiomer calcium salt showed far less potency than the racemic sodium salt – that is, the R-trans enantiomer of the calcium salt was less active than the racemate of the sodium salt. This difference should have been a red flag that something was wrong with the screen, likely a problem related to the difficulty with solubility of the compounds. Instead, Warner-Lambert used this questionable data to support the false claim that R-trans enantiomer has a tenfold greater inhibition of cholesterol synthesis than the racemate.

157. Warner-Lambert was aware of the numerous problems with CSI 118 identified above and knew that the results of CSI 118 were not scientifically sound. Yet, in the face of radically different value for the sodium and calcium salts, solubility problems, unknown solution concentrations, and results that showed the racemate of one salt was more potent than the R-isomer of another salt, Warner-Lambert used this inconsistent outcome to further substantiate his claim that the R-isomer was ten times more active than the racemate in inhibiting cholesterol synthesis.

158. Warner-Lambert's patent attorneys submitted the misleading and false CSI table generated by Roth and others and the misleading and false Roth Declaration to the PTO in support of the '995 Patent application.

2. Warner-Lambert Admits the Patent Specification Claims a Surprising Ten-Fold Increase in Activity

159. At numerous points in the prosecution of the '995 Patent, Warner-Lambert and Roth expressly stated that the activity of the R-trans enantiomer was both surprising and ten-

times greater than the activity of the racemic mixture. Nonetheless, in subsequent patent litigation, Roth and Warner-Lambert tried to shy away from admitting that Warner-Lambert had claimed that the surprising feature of the R-trans enantiomer was a tenfold increase in activity over the racemate. Warner-Lambert knew that both the CSI table and Roth Declaration presented false information about the activity of the R-trans enantiomer as compared to the S-trans enantiomer and the racemate. To acknowledge in court that the only claimed "surprising" characteristic was in fact false would result in the loss of the '995 Patent and/or its foreign counterparts.

160. Roth's evasive testimony on this topic is illustrative:

Q. I suggest to you that you either do or do not rely on those figures. If you want to put out a merely qualitative statement that you have surprising activity you can put it in words. If you put it out in figures that suggests that it is a very surprising level of activity, being a 10-fold difference?

A: But I believe the words we used were a surprising level of activity. We didn't say that it was surprising because it was a 10-fold difference. We simply said that it was surprising, the numbers suggest 10-fold. But frankly, again, anything more than twofold would be surprising. We didn't claim 10-fold in the patent. We said it was surprising.

Q: You didn't put a qualification to the numbers that you give in the patent to say "beware of these numbers. We're only really saying that we get a better than two-fold improvement"; no mention of that, was there?

A: What we say is that the compound has surprising activity and then we put data into the patent which supported the surprising level of activity. I don't think that we actually comment on the data except to say that it's surprising. The data is what the data is.

Q: The data on its face quantify that is surprising level of activity, does it not, Dr. Roth?

A: There are numbers given, yes.

Q: So it quantifies that surprising level of activity?

A: What do you mean by that?

Q: Do you know what the meaning of the word "quantifies" is?

A: There are numbers that are given. Again, we don't make any claims; all we say is that it's surprising. The numbers are what the numbers are.

161. Roth was ultimately forced to concede that the biological data contained in the patent specification purports to show a ten-fold increase in activity, and that it was included in the specification for that reason:

Q: And you wanted those numbers to be taken at face value, did you not?

A: I'm not sure I know what you mean.

Q: What?

A: The data is what the data is. The data was included to support the rising level of activity. What the numbers suggest is that it's something like 10-fold, but we don't state that. We simply – what we simply do is we say it's surprising.

Q: Isn't it a fair reading of this passage on page 8 that having said it's surprising that you are saying now here is why and you set out figures which show a 10-fold increase and you don't provide any qualification at all to those numbers?

A: That is true. We simply report the data.

162. Roth acknowledged "[t]he data is what the data is," "the numbers are what the numbers are," and "the data was included to support the surprising level of activity. What the numbers suggest is that it's something like 10-fold …." The numbers show, based on cherry-picked test results, regardless of whether particular words appear in the text of the patent, that the R-trans enantiomer is ten times more active than the racemate. In reality, the R-trans enantiomer is, as expected, only about twice as active as the racemate.

3. Warner-Lambert Intended for the PTO to Rely on the False Data and Claims

163. Roth has admitted under oath that he submitted CSI data for the purpose of supporting a surprising level of activity which therefore supported patentability: "the biological data that was included in the patent I felt demonstrated and supported a surprising level of biological activity."

> Q. So [the biological data] was put in to demonstrate this surprising level of activity for the purpose of obtaining a patent, was it not?
>
> A. Yes, I guess you would say that that would be true. I mean, the data supported a surprising level of activity, which we thought would be novel and surprising and therefore would support patentability.

F. FDA Approval: The FDA approves Lipitor and the Original Lipitor Patent Provides Years of Patent Protection

164. On June 17, 1996, Warner-Lambert submitted a new drug application under §505(b) of the Federal Food, Drug and Cosmetic Act ("FDCA") and §314.50 of Title 21 Code of Federal Regulations, seeking approval to sell atorvastatin calcium. The formulation developed for FDA approval and commercialization was atorvastatin calcium, *i.e.*, the isolated R-trans enantiomer formulated as a calcium salt. On December 17, 1996, the FDA approved atorvastatin calcium – named "Lipitor" – for the treatment of hypercholesterolemia and mixed dyslipidemia. The FDA initially approved 10 mg, 20, mg, and 40 mg tablets, adding approval of 80 mg tablets on April 7, 2000.

1. The Orange Book Listings for the '893 and '995 Patents

165. Following approval, Warner-Lambert listed both the '893 Original Lipitor Patent and the '995 Enantiomer Patent in the Orange Book. When it did so, Warner-Lambert knew that it had procured the '995 Enantiomer Patent through actual fraud on the PTO.

166. By listing both patents in the Orange Book, a generic company seeking approval for an ANDA for generic atorvastatin calcium would need to file a Paragraph IV certification as to both the '893 and '995 patents if it wished to enter the market before the expiration of the patents; such a certification would trigger Warner-Lambert's ability to file infringement litigation, which in turn would trigger the usual Hatch-Waxman statutory delays for FDA generic approval.

167. At the time of FDA approval of Lipitor, the '893 Original Lipitor Patent was scheduled to expire on May 30, 2006. The '995 Enantiomer Patent would not expire until on December 28, 2010.

168. Pfizer also owns (through subsidiaries) two process patents – U.S. Patent No. 6,087,511 ("the '511 patent") and U.S. Patent No. 6,274,740 ("the '740 patent") – that claim a process for making amorphous atorvastatin calcium that is limited to crystalline Form I atorvastatin calcium (the '511 patent and the '740 patent are collectively referred to as "the Process Patents"). Pfizer has not listed these patents in the Orange Book; it has sued to enforce these patents on only two occasions, against only two generic competitors. The Process Patents will expire in July 2016.

2. The '893 Original Lipitor Patent Protected the Lipitor Franchise for Years

169. Shortly after FDA approval**,** Warner-Lambert applied for an extension of the patent term of the '893 patent under 35 U.S.C. § 156. Section 156 provides that the period of patent protection may be extended in order to account for the time lag between the issuance of a patent covering the active ingredient in a new drug, and FDA approval.

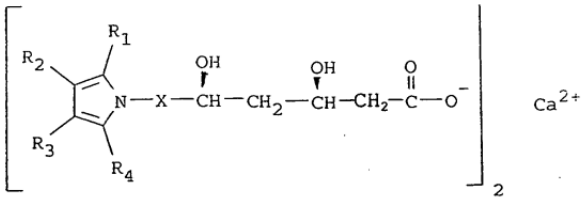
170. Warner-Lambert asked the PTO to extend Lipitor's period of market exclusivity granted by the '893 Original Lipitor Patent – not the '995 Patent – for about three years and four

months. That is, *Warner-Lambert took the position that the '893 Patent covered the isolated R-trans enantiomer, atorvastatin, in calcium salt form.*

171. Warner-Lambert informed the PTO that (i) the FDA approved Lipitor, (ii) the active ingredient in the drug Lipitor is atorvastatin calcium, and (iii) atorvastatin calcium is covered by the '893 Patent. Warner-Lambert claimed that the '893 Original Lipitor Patent claims atorvastatin calcium as a new chemical entity (Claims 1-4), as a pharmaceutical composition (Claim 8), and a method for using it to inhibit cholesterol biosynthesis (Claim 9).

172. Claim 1 requires "a compound of structural formula I" or "a hydroxyl acid or pharmaceutically acceptable salt thereof, corresponding to the opened lactone ring of the compounds of structural formula I above." In the extension application, Warner-Lambert claimed that Lipitor is a pharmaceutically acceptable salt of structural formula I, and thus covered by Claim 1 of the Original Lipitor Patent:

> Lipitor is a pharmaceutically acceptable salt (i.e., calcium salt) of the hydroxy acid corresponding to the opened lactone ring of a compound of structural formula I. Lipitor has the general structure:



where: X is $-CH_2CH_2-$

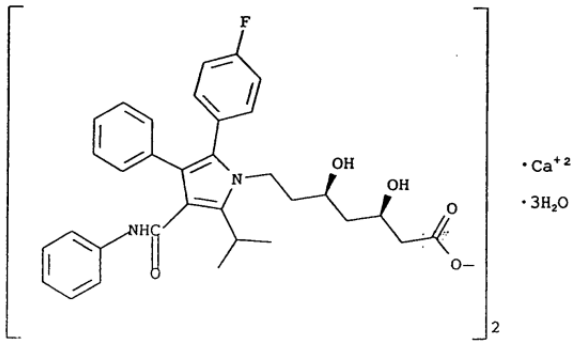
R_1 is 4-fluorophenyl;

R_2 is phenyl;

R_3 is -CONH-phenyl; and

R_4 is 1-methylethyl, an alkyl group having three carbon atoms.

Lipitor™ thus has the specific chemical structure



173. The PTO granted the patent term extension. With both an extension for its delay in FDA approval, and for pediatric testing, the '893 Original Lipitor Patent would expire on March 24, 2010.

174. Warner-Lambert also sought and obtained a six-month extension for pediatric testing for the '995 Enantiomer Patent. As a result, the expiration date of the '995 Enantiomer Patent is June 28, 2011.

175. In effect, the '893 Original Lipitor Patent would provide more than fourteen years of patent exclusivity to market and sell branded Lipitor – from the 1997 launch until March of 2010. The fraudulently obtained '995 patent would tack on, if enforced by Warner-Lambert or its successors, almost another year-and-a-half of exclusive Lipitor profits.

3. The 1997 Launch of Lipitor

176. Prior to commercialization, Warner-Lambert faced serious challenges in bringing Lipitor to market. Lipitor would be the fifth statin available to patients and physicians. One of Lipitor's biggest challenges was to overcome the perception that it was a "me-too" product. Merck and Bristol-Myers Squibb, the primary incumbents, already had proven products in the market.

177. Warner-Lambert wanted to employ a "saturation" approach to selling Lipitor, an essential approach because the medical community largely was content with the drugs already available to treat high cholesterol. The intent of the "saturation" strategy was to have as many sales representatives as possible contacting physicians. As Anthony Wild, Warner-Lambert Pharmaceutical Sector President, explained, "[t]he more soldiers you have out there, the more guns, the more likely you are to achieve your ends." Warner-Lambert clearly understood that the sales force was a key success factor in any drug's performance, but a 1995 sales force deployment study revealed that the Warner Lambert's sales force was inadequate in size and focus to effectively launch Lipitor.

178. Warner-Lambert chose Pfizer to help market Lipitor. Warner-Lambert and Pfizer outgunned the competition with the largest statin sales force ever. Between Warner-Lambert and Pfizer, more than 2,200 sales representatives were believed to be selling Lipitor at the time of its U.S. launch.

179. After launching in January 1997, Lipitor reached $1 billion in domestic sales within its first 12 months on the market. By the end of 1998, Lipitor was available for sale in 50 countries. Lipitor claimed U.S. market share leadership in the statin drug class in October 1997 with a 30% share of all new statin prescriptions. Pfizer would later acquire Warner-Lambert.

G. Patent Litigation: Pfizer Sues for Infringement of the '995 Patent to Keep Generics off the Market

180. Pfizer used the '995 patent to delay the efforts of at least four generic manufacturers that sought approval to manufacture and sell generic atorvastatin calcium. The generic pharmaceutical manufacturers who have filed and are seeking to sell generic versions of Lipitor, and which have been sued for infringement of the '995 Enantiomer Patent, are: Ranbaxy, Teva Pharmaceuticals USA, Inc. ("Teva"), Cobalt Pharmaceuticals Inc. ("Cobalt") and Apotex Inc. ("Apotex"). But for the commencement of these actions by Pfizer, generic atorvastatin calcium would have been available no later than March 24, 2010, that is, upon expiration of the '893 Original Lipitor Patent.

1. *Pfizer v. Ranbaxy*, 03-CV-209-JJF

181. Ranbaxy was the first to file an ANDA for generic atorvastatin. Ranbaxy was also the first stymied by Pfizer's sham litigiousness in claiming infringement of the '995 Enantiomer patent.

182. In early 2003, Ranbaxy filed ANDA 76-477, seeking approval to sell a generic version of Lipitor. As the first to file an ANDA for generic atorvastatin calcium, Ranbaxy acquired the exclusive right to manufacture and sell generic Lipitor for the first six months following the expiration of relevant, valid Lipitor patents.

183. On February 28, 2003, Ranbaxy sent two paragraph IV certification letters to Pfizer with respect to the '893 and '995 patents. In these letters, Ranbaxy asserted that no valid patent claims covering Lipitor would be infringed by the sale, marketing, or use of Ranbaxy's generic product.

184. On February 21, 2003, Pfizer filed an action in the United States District Court for the District of Delaware alleging infringement of the '893 and '995 patents. Pfizer alleged Ranbaxy's ANDA amounted to infringement of the '893 and '995 patents.

185. From 2003 to 2007, the '893 and '995 Ranbaxy infringement litigation progressed through discovery, a jury-waved trial and an eventual appeal and decision by the United States Court of Appeals for the Federal Circuit. Multiple factual issues for both the '893 and the '995 patent were litigated as between Ranbaxy and Pfizer. (Of course, the Plaintiff here and the proposed Direct Purchaser Class were not parties to that litigation and are not bound by any of the determinations made in that litigation).[12]

186. On August 2, 2006, the Federal Circuit reversed the lower court's decision regarding the '995 patent, determining that claim six of the patent was technically invalid.[13] The Federal Circuit did not address the district court's other determinations. The Federal Circuit affirmed that Ranbaxy had infringed the '893 patent and upheld that patent's time extension. The district court confirmed this decision on remand, and granted Pfizer exclusivity for Lipitor until the expiration of the '893 patent.

187. In light of the technical ruling by the Federal Circuit on claim 6 of the '995 Enantiomer Patent, Pfizer filed with the PTO amendments to the '995 Enantiomer Patent in order to correct the technical nomenclature error that led to the invalidity of claim 6 of the '995 Enantiomer Patent. In light of that proceeding, Ranbaxy remained foreclosed from entering the

[12] Among the numerous issues litigated before the district court in the jury-waved trial between Ranbaxy and Pfizer was the early form of the evidence adduced by Ranbaxy regarding inequitable conduct by Warner-Lambert in the procurement of the '995 Enantiomer Patent; on that record as between those parties, Pfizer prevailed. The issue of Warner-Lambert's representations regarding the biological activity of the R-trans enantiomer as compared to its racemate have also been litigated in other fora worldwide. There, when addressed after a more fully developed record, Pfizer lost on the issues relating to the integrity of the "surprising" data for the enantiomer.

[13] The PTO more recently accepted Pfizer's application to correct a technical defect in claim two of patent no. 5,273,995, which would presumably repair the invalidity of claim six. In March 2009, the PTO allowed the reissue of the patent as no. RE40,667, which retained the expiration date of June 28, 2011.

market for atorvastatin calcium by reason of Pfizer's continued assertion of patent protection by the '995 Enantiomer Patent.

188. On March 24, 2008, Pfizer instituted a second action against Ranbaxy, citing the February 28, 2003 letter from Ranbaxy informing Pfizer of Ranbaxy's filing of ANDA 76-477 regarding the '995 patent. This time, Pfizer's lawsuit focused on the two Process Patents (i.e., the '740 and '511). As process patents, neither of these patents are listed in the Orange Book and thus the patents do not implicate the usual paragraph certification and statutory stay provisions of the Hatch-Waxman Act. As a practical matter, neither of these two process patents posed any legitimate threat of infringement to Ranbaxy. The '995 Enantiomer Patent presented the bar to entry.

189. On June 17, 2008, Ranbaxy and Pfizer settled their differences, but under terms that where themselves anticompetitive. The implications for this settlement are more fully set forth later, and as we will see, this agreement was a sham and part of Pfizer's overarching scheme to unlawfully delay the introduction of generic Lipitor until November of 2011. And because Ranbaxy was first to file an ANDA for Lipitor, in most circumstances all other generic entrants would need to await Ranbaxy's entry.

190. But for Warner-Lambert's fraud in procuring the '995 Enantiomer Patent, the '995 Enantiomer Patent never would have issued. Furthermore, but for the fraud of Warner-Lambert, Ranbaxy would have entered the market for atorvastatin calcium on or about the end of March of 2010. Since Pfizer acquired the fraudulently procured '995 Enantiomer Patent, Pfizer was able to use that patent to unlawfully delay Ranbaxy's entry into the market for atorvastatin calcium for a period of at least fourteen months, and likely longer. Moreover, it is likely, absent

the ability of later generics to get rapid decisions in patent infringement litigation, that all potential generic entrants will be delayed by reason of Ranbaxy's delay.

2. *Pfizer v. Teva,* 07-CV-360 (D. Del. 2007).

191. On April 24, 2007, pursuant to Hatch-Waxman, Teva notified Pfizer it had filed ANDA 78-773 seeking approval to sell a generic version of Lipitor. Teva included a Paragraph IV certification that the '995 Enantiomer patent was invalid, unenforceable, or would not be infringed by Teva's proposed generic product.

192. On June 7, 2007, Pfizer responded by filing an action in the United States District Court for the District of Delaware against Teva alleging infringement of the '995 patent (excepting claim 6). As a result of this suit, the parties reached a settlement on July 15, 2009, whereby Teva would not seek approval for its generic product for a certain period of time.

193. But for Warner-Lambert's fraudulent procurement of '995 Enantiomer Patent, there would be entry in the market for generic atorvastatin calcium by Teva by September of 2010.

3. *Pfizer v. Cobalt*: 07-CV-790 (D. Del. 2007).

194. At some time prior to December of 2007, pursuant to Hatch-Waxman, Cobalt notified Pfizer of its application, seeking FDA approval to market atorvastatin, and a Paragraph IV certification that the '995 Enantiomer patent was invalid, unenforceable, or would not be infringed by Cobalt's proposed generic product.

195. On December 6, 2007, Pfizer filed an action in the United States District Court for the District of Delaware against Cobalt alleging infringement of the '995 Enantiomer patent (excepting claim 6). In consenting to judgment on May 15, 2008, Cobalt admitted the '995 patent would be infringed by the product proposed in its NDA. The consent also restricted the

effective date of any approval of NDA 22-245 to be no earlier than the expiration of the '995 patent.

196. But for Warner-Lambert's fraudulent procurement of '995 Enantiomer Patent, Colbalt would launch a formulation of atorvastatin by September of 2010.

4. *Pfizer v. Apotex*, 08-CV-7231 (N.D. Ill. 2008).

197. On November 4, 2008, pursuant to Hatch-Waxman, Apotex notified Pfizer of its ANDA 90-548, seeking FDA approval to market atorvastatin calcium, and Paragraph IV certification that Pfizer's patent nos. 5,273,995, 6,126,971, 5,686,104, and 5,969,156 were invalid, unenforceable, or would not be infringed by Apotex's proposed generic product.

198. On December 17, 2008, Pfizer responded by filing an action in the United States District Court for the Northern District of Illinois, Eastern District, against Apotex alleging infringement of the '995 Enantiomer Patent.

199. But for Warner-Lambert fraudulent procurement of '995 Enantiomer Patent, Apotex would enter the market for generic atorvastatin calcium by Apotex by September of 2010.

H. The '995 Reissuance Process Itself Becomes Another Chapter In the Scheme to Delay Generic Entry

200. Without Warner-Lambert's fraud on the PTO during the initial prosecution of the '995 patent, the '995 patent never would have issued. Without the '995's additional period of patent protection, generic versions of atorvastatin would have been available on March 24, 2010 when the '893 Patent's additional marketing exclusivities expired – marketing exclusivities that were granted because the '893 patent covered Lipitor.

201. That Pfizer later went back and sought reissuance on the '995 patent to correct a technical defect in its claims – claims that were only ever found patentable because of Warner-

Lambert's fraudulent claim that the R-trans enantiomer was ten times more active than the racemate – cannot change the fact that the '995 patent would never have initially issued but for Defendant's fraud. Without the *original issuance* of the '995, there could be no *reissuance* of it.

202. The reissuance proceedings actually confirm what Warner Lambert had long known: the biologic data submitted as part of the application for the '995 Enantiomer Patent is false, inaccurate, incorrect, and riddled with errors. Throughout the reissue proceedings Pfizer eschews all reliance on biological data (including CSI data), at one point explicitly acknowledging that the biological data originally used to support patentability was "inaccurate."

203. Rather than submit "corrected" biological data, Pfizer takes an entirely new tact: Pfizer argues that Lipitor is entitled to additional protection under the '995 patent because of Lipitor's overwhelming commercial success. But Pfizer's commercial success argument is no more viable than their "surprising activity" argument was the first time around.

1. Defendants Admit the Biologic Data is False

204. In January 2007, in the wake of the Federal Circuit invalidating Claim 6 of the '995 Enantiomer Patent on technical grounds, Pfizer sought re-issuance of the '995 Patent "to correct a technical defect in some of the patent claims…"

205. Pfizer knew, as a result of international patent litigation, that it could no longer publicly rely on the falsified biological data Warmer-Lambert had submitted to the PTO back in 1989-1993. As a result, during the reissuance proceedings Pfizer expressly disavowed reliance on the 1989-1993 biological data, including the data presented in the CSI table and Roth Declaration.

206. In the absence of Warner-Lambert's original fraud on the PTO, the '995 Enantiomer Patent would never have issued. Without the '995 Patent being issued in 1993, no

reissue proceeding for a '995 Patent in years 2007-2009 would be possible. As a result, the PTO's eventual decision on these re-issue proceedings is irrelevant to this antitrust action.

207. The reissue proceedings, do however, confirm what Defendants had long known: the biologic data submitted as part of the application for the '995 Enantiomer Patent is false, inaccurate, incorrect, and riddled with errors.

208. On January 16, 2007, Roth and Pfizer submitted the Claim 6 '995 reissue application. The applicants did not amend or modify the '995 Patent specification as part of the reissue proceedings. Roth's remarks include a list of the "objective evidence" that "completely refutes any suggestion of obviousness." But now, the list does **not** include the purported surprising effectiveness of the R-trans enantiomer or a ten times greater activity of the R-trans enantiomer than the racemate.

209. Pfizer's Informational Disclosure Statement eschewing reliance on CSI and COR biological data:

> Subsequent to the Federal Circuit's decision, while preparing for trial in Australia on a '995 counterpart, Pfizer first learned of significant errors in the COR results which neither Pfizer nor the parties adverse to it had discovered before. This discovery led Pfizer to advise the Federal Circuit that COR data could not be relied on to compare the relative activity of compounds – see Exhibit 9, page 10, fn 2. Thus any earlier reference in Pfizer's findings, conclusions and brief to relative activity among compounds based on the COR test is withdrawn and is not relied on in these reissue proceedings. *Pfizer does not at this point in the reissue rely for patentability on any comparisons based on CSI*. Neither CSI no COR data were relied on by either U.S. court in reaching their decisions regarding the validity of '995 claim 6."

Pfizer similarly states, "Pfizer does not now rely on any …data [comparing between and among calcium salts and other salts of atorvastatin and its racemates] in support of patentability."

210. On June 7, 2007, Defendants submitted a Second Informational Disclosure Statement that discusses "Foreign Proceedings on '995 Counterparts" and attached additional

materials produced as part of certain non-U.S. proceedings. Pfizer acknowledges therein that the biological data submitted in support of its patent applications – in the CSI Table, the Roth Declaration, and the foreign "'995 counterparts" – is inaccurate:

> [A]pplicant is submitting these documents to permit the Examiner to consider their potential materiality. Further, many of these documents … contain biological data or summaries of biological date, and *some of that biological data is now understood to be inaccurate* (due to transcription errors, calculation errors, experimental errors, etc.). Applicant is not submitting *corrected* biological data at the present time because, as applicant has emphasized repeatedly in these reissue proceedings, applicant is not currently relying on the biological data for patentability. (emphasis added.)

211. Elsewhere in the reissue proceedings, Roth and Pfizer refer to the biological data at issue in the Australian and Canadian patent litigation as "biologic data that Pfizer *then* argued showed that the atorvastatin enantiomer had unexpected and surprising inhibition of cholesterol biosynthesis in-vitro in comparison to the racemic form of atorvastatin," while reiterating that they *"are not relying on any of the biological data as a basis for the patentability of the pending claims at the present time."* Similarly, Roth and Pfizer state, "[a]pplicant is not submitting *corrected* biological data at the present time because, as applicant has emphasized repeatedly in these reissue proceedings, applicant is not currently relying on the biological data for patentability."

212. At one point during the reissue proceedings, the examiner relied on the biological data to overcome an obviousness rejection:

> Claims 6, 13 and 14 have not been rejected as being obvious as the declaration of Bruce D. Roth filed February 25, 1991 discloses unexpected properties which would overcome any 35 USC 103(a) rejection of claims 6, 13 and 14 as *atorvastatin calcium was shown to have activity greater than fifty-fold more than that of the S-trans and at least ten-fold more than that of the racemate.*

213. In response, Pfizer reiterated that it was "not presently relying on any of the biological data (including the data contained in the Roth Declaration) as support for the patentability of claims 6, 13 and 14." Pfizer acknowledged that the examiner relied on the Roth Declaration and asked her to "withdraw her reliance on the data in the Roth Declaration" and focus on Pfizer's new argument: that it was entitled to additional patent protection based on Lipitor's commercial success.

214. On April 24, 2008, the PTO issued a non-final rejection of claims 6, 13, and 14. In so doing, the Examiner formally withdrew her reliance on the Roth Declaration. Instead, the Examiner relied on secondary considerations identified by the Applicants, namely Lipitor's commercial success.

215. On April 6, 2009, the PTO reissued claims 6, 13, and 14 of the '995 Patent ("'667 Patent").

2. Lipitor's Commercial Success Has No Bearing on Whether the Invention Claimed by the '995 Patent is Obvious

216. The PTO based its ruling to grant the re-issuance of the '995 Enantiomer Patent not on the basis of the biological studies and representations made by Warner-Lambert (even though a version of the CSI assay data remains in the specification for the patent), but instead on Pfizer arguments that the commercial success of Lipitor shows that the '995 Enantiomer Patent could not have been obvious.

217. Pfizer's argument that Lipitor's commercial success means that the invention claimed in the '995 patent could not be obvious over the Original Lipitor Patent was emphatically wrong as a matter of fact and law.

218. First, Lipitor was commercially successful during the 1997-2010 time period, a time period during while it enjoyed patent protection under *both* the '893 Original Lipitor Patent

and the '995 Enantiomer Patent. Lipitor was *not* commercially successful while enjoying patent protection *solely* under the '995 Enantiomer Patent. Since the question of obviousness at issue is whether or not the '995 Patent is obvious when compared to the '893 Patent, the fact that Lipitor, which is covered by *both* patents, has been commercially successful generally, provides *no* meaningful information at all in terms of the distinctions *between* the two patents.

219. Second, Pfizer's "commercial success" of Lipitor argument is a claim about Lipitor's success when compared to other statins, or in terms of growing overall statin use. When Pfizer boasts about Lipitor being the most successful pharmaceutical of all time, or of Lipitor gaining the largest market share of amongst all statins, the comparisons are between Lipitor and *other statins*, or to the growing of the *statin market generally*. But the issue of obviousness in this particular situation is not a comparison of Lipitor to other statins, or of Lipitor to growing statin use. Instead, here the correct issue of patent obviousness is whether or not the invention under the '995 Enantiomer Patent would have been successful as *compared to an invention under the '893 Original Lipitor Patent*. However, because *both* the '893 and '995 patents cover the *same* product, looking to Lipitor's general success, or its success compared to other statins, provides no elucidation whatsoever as to whether the '995 Patent is obvious as compared to the '893 Patent. To have any kind of a meaningful "commercial success" information that relates to the pertinent patent question, there must be a comparison of an invention under the '995 Patent as compared to a *different* invention under the '893 Patent. There is none.

220. In summary, Pfizer and its predecessors obtained, by actual fraud, the '995 Enantiomer Patent. If that actual fraud had not been committed during the prosecution for the '995 Patent back between 1989 and 1993, the '995 Enantiomer Patent simply would not exist,

and no other argument could or would have been made whether or not the '995 Patent was legitimate.

221. Without the '995 Patent, generic makers, many of whom filed their ANDAs quite long ago, would have entered the market for generic atorvastatin calcium back in March of 2010. Pfizer and its predecessors have unlawfully foreclosed the market for generic versions of Lipitor. Upon market entry of generic Lipitor, it is estimated that U.S. consumers, the government, and TPPS could save between $10.0 million and $18.6 million *per day*, or roughly $3.97 billion to *$6.8 billion in potential savings a year*.

I. Pfizer and Ranbaxy Conspire to Divide Markets and Cause Reissuance of the '995 Patent

222. After years of litigation, and in the context of the ongoing reissuance and Process Patents battles, Pfizer and Ranbaxy capitalized on the opportunity to ostensibly resolve the pending disputes through arrangements which were themselves independently unlawful and anticompetitive.

223. Back in August 2002, Ranbaxy (the largest pharmaceutical manufacturer in India) had been the first to file an ANDA for U.S. sales of generic atorvastatin calcium, and it was the first to make paragraph IV certifications as to all five patents listed at that time – the '893, '995, '104, '156, and '971 patents. In 2003, Pfizer had sued Ranbaxy only for infringement of the '893, and the '995 patents. *See Pfizer Inc. v. Ranbaxy Laboratories Ltd.*, 03-cv-209 (D.Del. 2003) ("*Ranbaxy*").

224. Because it was the first to file an ANDA with paragraph IV certification for each listed patent, the Hatch-Waxman Act afforded Ranbaxy a 180-day exclusivity period to sell a generic version of Lipitor beginning on the earlier of (1) the date that of first commercial marketing of the drug, or (2) for each listed patent, on the date of a final court judgment

declaring that patent invalid, unenforceable, or not infringed. During this 180-day exclusivity period, no other drug manufacturer can market a generic Lipitor product, with the exception of an authorized generic.

225. Because Pfizer listed the '104 and '971 patents in the Orange Book but did not file patent infringement suits against any generic ANDA filers who submitted paragraph IV certifications to those patents, Pfizer was able to ensure that (1) Ranbaxy's first-to-file exclusivity would not be triggered by a court decision, and (2) Pfizer could prevent the launch of all other generics for an indefinite period by entering into an anticompetitive agreement with Ranbaxy whereby Ranbaxy agrees to delay the launch of its generic product.

226. Ranbaxy's first-to-file exclusivity has never been triggered because (1) Ranbaxy has not yet begun to market its product, and (2) no court decision of non-infringement or invalidity had been issued with respect to the '104, '156, and '971 patents.

227. Because Pfizer did not list the Process Patents in the Orange Book, those patents never included in any generic manufacturers' paragraph IV certification. Pfizer could not obtain the Hatch-Waxman 30-month stay by bringing an infringement claim on these patents.

228. Ranbaxy and one other generic manufacturer, Mylan Pharmaceuticals Inc., were the only companies that Pfizer ever brought infringement actions against for the Process Patents. The lawsuit against Mylan was settled before the Court could make any substantive ruling on either process patent, and the terms of the settlement have not been publicly disclosed.

229. During the *Ranbaxy* action, Pfizer moved for leave to amend its pleadings to add claims, under 35 USC §271(g), that Ranbaxy had also intended to infringe the Process Patents. Pfizer requested a declaratory judgment of infringement under 28 USC § 2201. Ranbaxy opposed Pfizer's motion to add the Process Patent claims, arguing that Pfizer had not made a

sufficient allegation of immediacy and reality to establish the existence of an actual controversy (D.I. 44).

230. In an opinion issued in April 2004, the *Ranbaxy* Court agreed with Ranbaxy, stating that, "because of the uncertainty surrounding Ranbaxy ANDA efforts, Pfizer's attempt to join claims under its '511 and '740 patents by invoking the Declaratory Judgment Act, 28 U.S.C. §2201, are premature." The Court further found that "waiting for any claims involving Ranbaxy's manufacturing process to mature so that such claims comport with the immediacy and reality standard will not prejudice Pfizer in any way" (D.I. 139).

231. After the 2005 bench trial and the August 2006 Federal Circuit ruling, Pfizer's patent protection for Lipitor had been shortened from June 28, 2011 (derived from the invalidation of claim 6 of the '995 patent) to March 24, 2010, the expiration date for the '893 patent.

232. In January 2007 when Pfizer filed the '995 reissue application, it sought to extend patent protection for Lipitor until June 28, 2011 (the expiry of the '995 patent which was then rendered invalid).

233. In May 2007, Ranbaxy filed a protest with the PTO against Pfizer's reissue application.

234. In August 2007, the PTO issued a First Office Action rejecting Pfizer's reissue application on grounds set forth in Ranbaxy's protest—that certain claims in the '995 patent were anticipated, obvious, or constituted double-patenting.

235. Pfizer then filed a response to the PTO's initial Office Action, which was again rejected by the PTO in April 2008.

236. Consequently, Ranbaxy intended to enter, and could have entered, the market with its generic immediately after March 24, 2010.

237. On March 24, 2008, nearly five years after it first attempted to attach the process patents to the *Ranbaxy* case, and knowing that a court had already ruled that it lacked standing under 28 U.S.C. §§2201 and 2208, Pfizer again sued Ranbaxy for declaratory judgment of infringement of the Process Patents on *the same grounds* as those on which it based its original motion to amend the *Ranbaxy* case pleadings. *See Pfizer Inc. v. Ranbaxy Laboratories Ltd.*, 08-cv-164 (D.Del. 2008) (D.I. 1, ¶¶ 31, 41).

238. Ranbaxy moved to dismiss for lack of subject matter jurisdiction arguing that the final judgment in the *Ranbaxy* case, which permanently enjoined Ranbaxy from engaging in the manufacture, use, offer to sell or sale of its generic version of Lipitor until the expiration of the '893 patent, made "any harm to Pfizer from alleged infringement of the '511 and '740 patents *much less* imminent now than in the [*Ranbaxy*] case when the Court found no imminent threat of harm or injury." (D.I. 10 at 9).

239. The court never had an opportunity to make a substantive ruling on Ranbaxy's motion to dismiss because on June 18, 2008, the parties filed a consent order resolving the lawsuit. (D.I. 19). The consent order referred to an agreement between Pfizer and Ranbaxy, dated June 17, 2008, "pursuant to which the parties have resolved this action and Pfizer has granted Ranbaxy certain rights to its portfolio of patents relating to atorvastatin." (the "Agreement") *Id.*

240. On or about June 18, 2008, Pfizer announced that it had entered into the Agreement with Ranbaxy to settle the *Ranbaxy* Case.

241. As of the date of the Agreement, Ranbaxy's 180-day exclusivity period with respect to the '995 patent had been triggered and had expired, and its 180-day exclusivity period with respect to the '893 patent was set to automatically terminate on the expiration of that patent on March 24, 2010.

242. As of the date of the Agreement, there was no Hatch-Waxman impediment that would have prevented a generic Lipitor launch by Ranbaxy, whether independently or in association with another manufacturer, on or after March 24, 2010.

243. And as of the date of the Agreement, the only means by which Pfizer could have prevented a launch by Ranbaxy on or after March 24, 2010 was by seeking an injunction. As far as Pfizer knew in 2008, obtaining such an injunction would have required a showing that Pfizer was likely to succeed on the merits of patent infringement claims that it had never previously asserted against Ranbaxy.

244. Under the terms of the Agreement, Ranbaxy was given a license to sell generic versions of Lipitor in the United States, effective November 30, 2011 — twenty months after the then-sole-principal and valid patent on Lipitor (the '893 patent) would have expired and Ranbaxy would have otherwise been able to sell its generic. Ranbaxy was also given a license to sell generic versions of Lipitor on varying dates in several additional countries.

245. As additional consideration to enter into the Agreement, Pfizer forgave debts owed by Ranbaxy flowing from a court judgment or judgments Pfizer won against Ranbaxy on infringement claims unrelated to the Lipitor patents.

246. The Agreement further provided that Ranbaxy would refrain from any further challenges to the validity of patents related to Lipitor, including the reissue application for the '995 patent then pending before the PTO.

247. In January 2009, the PTO, without any objection by Ranbaxy, issued a Notice of Allowance accepting Pfizer's application for the '995 patent and reissuing the same as the '667 patent. This Notice of Allowance extended Pfizer's patent protection for Lipitor until June 28, 2011. The notice would not have issued had Ranbaxy maintained its protest – since there were no logical grounds to grant the application, Pfizer's sophistry to the PTO (regarding the irrelevant observations about the commercial success of Lipitor) would have been disclosed as lacking all merit.

248. By delaying Ranbaxy's generic version of Lipitor in the United States — which, in the absence of the Agreement, would have been sold lawfully as early as March 24, 2010 (but in no event later than the '995 expiry in June 28, 2011) — Pfizer was able to sell Lipitor exclusively for up to 20 additional months, resulting in extra sales of Lipitor worth approximately $10 billion dollars. In return, Pfizer granted Ranbaxy the right to distribute a generic substitute for Lipitor in foreign markets earlier than it would have been able to do so otherwise.

249. The Agreement denies purchasers, including Plaintiff and the Class, access to a generic substitute for Lipitor in the United States for up to 20 months following the expiration of the '893 patent. Lipitor's current price exceeds $4 per day, while a generic version will sell for between $0.25-$0.35 and even as low as $0.10. Consequently, Lipitor purchasers in the United States are paying, and will continue to pay, inflated prices for Lipitor through at least May of 2012.

250. By reason of these unlawful agreements, there is presently no generic competitor to Lipitor in the United States market. Prices for Lipitor are substantially higher since March 2010 than they would have been but for the Agreement.

251. Ranbaxy intends to launch its generic version of Lipitor in the American market in November 2011 risk-free and with market exclusivity for 180 days.

252. The Agreement between Defendants, which artificially extended Pfizer's exclusivity in the domestic atorvastatin calcium market, allocated markets between the Defendants, artificially postponed price reductions, and restrained trade in the provision of Lipitor and its generic alternatives, is a violation of the Sherman Act.

253. The Agreement between Pfizer and Ranbaxy is an agreement to divide markets in that Ranbaxy agreed that it would not sell its generic in the United States until November 2011 in exchange for being able to sell in other countries.

254. The Agreement between Pfizer and Ranbaxy is an agreement to fix prices in that Pfizer would be able to charge many times more for Lipitor than it would otherwise have been able to charge in the absence of the unlawful agreement.

255. The Agreement between Pfizer and Ranbaxy is a combination to monopolize, an attempt to monopolize, and monopolization in that the Agreement unlawfully extends Pfizer's exclusivity in the domestic atorvastatin calcium market, excludes competition by other generics, and fixes the price of both the generic and branded versions of Lipitor.

256. The Agreement between Pfizer and Ranbaxy is alleged to restrain trade in that Pfizer allows Ranbaxy to sell generic Lipitor in countries other than the United States so long as it does not sell generic Lipitor in the United States, and forgives judgment debts that Ranbaxy owes to Pfizer as a result of unrelated patent disputes between the Defendants.

257. The Agreement between Pfizer and Ranbaxy is an abuse of the Hatch-Waxman Act in that it unlawfully delays the start of Ranbaxy's period of exclusivity and Ranbaxy agreed

to misuse its exclusivity to delay other generic competitors from entering the market with their generic Lipitor products.

258. The Process Patent litigation was a sham designed to create the false impression to outsiders that Ranbaxy had incentive to enter into the Agreement with Pfizer in order to avoid potential damages resulting from losing that litigation when, in fact, there was no real case or controversy and, consequently, Ranbaxy faced no real risk.

259. The Agreement meant that purchasers would continue to pay branded pharmaceutical prices for Lipitor longer than necessary.

260. The Agreement between Defendants extending the length of the Lipitor patents constitutes fraudulent procurement and enforcement of a patent in violation of the Sherman Act.

261. The Agreement between Defendants constitutes a market allocation agreement between competing providers of Lipitor and its generic equivalent to illegally restrain trade in violation of the Sherman Act.

VI. INTERSTATE COMMERCE

188. Defendants' efforts to monopolize and restrain competition in the market for atorvastatin calcium have substantially affected interstate and foreign commerce.

189. At all material times, Defendants manufactured, promoted, distributed, and sold substantial amounts of Lipitor in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

190. At all material times, Defendants transmitted funds as well as contracts, invoices and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Lipitor.

191. In furtherance of their efforts to monopolize and restrain competition in the market for atorvastatin calcium, Defendants employed the United States mails and interstate and

international telephone lines, as well as means of interstate and international travel. The activities of Defendants were within the flow of and have substantially affected interstate commerce.

VII. MONOPOLY POWER AND MARKET DEFINITION

192. At all relevant times, Pfizer had monopoly power over Lipitor and its generic equivalents because they had the power to maintain the price of Lipitor at supracompetitive levels without losing substantial sales.

193. A small but significant, non-transitory price increase by Pfizer of Lipitor would not have caused a significant loss of sales.

194. Lipitor does not exhibit significant, positive cross-elasticity of demand with respect to price, with any product other than AB-rated generic versions of Lipitor.

195. Because of, among other reasons, its use and varying ability to inhibit the production of cholesterol, Lipitor is differentiated from all products other than AB-rated generic versions of Lipitor.

196. Pfizer needed to control only Lipitor and its AB-rated generic equivalents, and no other products, in order to maintain the price of Lipitor profitably at supracompetitive prices. Only the market entry of a competing, AB-rated generic version of Lipitor would render Defendants unable to profitably maintain their current prices of Lipitor without losing substantial sales.

197. Pfizer also sold Lipitor at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

198. Pfizer has had, and exercised, the power to exclude competition to Lipitor.

199. Pfizer at all relevant times enjoyed high barriers to entry with respect to Lipitor.

200. To the extent that Plaintiff is legally required to prove monopoly power circumstantially by first defining a relevant product market, Plaintiff alleges that the relevant market is all atorvastatin calcium products – *i.e.*, Lipitor (in all its forms and dosage strengths) and AB-rated bioequivalent atorvastatin calcium products. During the period relevant to this case, Pfizer has been able to profitably maintain the price of Lipitor well above competitive levels.

201. The relevant geographic market is the United States and its territories.

202. Defendants' market share in the relevant market was 100% at all times.

VIII. MARKET EFFECTS

203. The acts and practices of Pfizer, and then later Ranbaxy with it, had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Lipitor from generic competition. Defendants' actions allowed Defendants to maintain a monopoly and exclude competition in the market for Lipitor and its AB-rated generic equivalents, to the detriment of Plaintiffs and all other members of the Direct Purchaser Class.

204. Defendants' exclusionary conduct has delayed generic competition and unlawfully enabled Defendants to sell Lipitor without generic competition. But for Defendants' illegal conduct, one or more generic competitors would have begun marketing AB-rated generic versions of Lipitor much sooner than they actually will be marketed, and, at all events, would have been on the market no later than March 24, 2010.

205. The generic manufacturers seeking to sell generic Lipitor had extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs and marketing generic pharmaceutical products.

206. Defendants' illegal acts to delay the introduction into the U.S. marketplace of any generic version of Lipitor caused Plaintiffs and the Class to pay more than they would have paid for atorvastatin calcium products, absent Defendants' illegal conduct.

207. Typically, generic versions of brand-name drugs are initially priced significantly below the corresponding reference listed drug ("RLD") branded counterpart to which they are AB-rated. As a result, upon generic entry, direct purchasers purchases of branded drugs are rapidly substituted for generic versions of the drug for some or all of their purchases. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further because of competition among the generic manufacturers, and, correspondingly, the brand name drug continues to lose even more market share to the generics. This price competition enables all direct purchasers of the drugs to: (a) purchase generic versions of a drug at substantially lower prices, and/or (b) purchase the brand name drug at a reduced price. Consequently, brand name drug manufacturers have a keen financial interest in delaying the onset of generic competition, and purchasers experience substantial cost inflation from that delay.

208. If generic competitors had not been unlawfully prevented from earlier entering the market and competing with Defendants, direct purchasers, such as Plaintiff and members of the Class, would have paid less for atorvastatin calcium by (a) substituting purchases of less-expensive AB-rated generic Lipitor for their purchases of more-expensive branded Lipitor, (b) receiving discounts on their remaining branded Lipitor purchases, and (c) purchasing generic Lipitor at lower prices sooner.

209. Moreover, due to Defendants' conduct, other generic manufacturers were discouraged from and/or delayed in developing generic versions of Lipitor.

210. Thus, Defendants' unlawful conduct deprived Plaintiffs and the Class of the benefits of competition that the antitrust laws were designed to ensure.

IX. ANTITRUST IMPACT

211. During the relevant period, Plaintiff and members of the Class purchased substantial amounts of Lipitor from Pfizer. As a result of Defendants' illegal conduct, members of the Class were compelled to pay, and did pay, artificially inflated price for their atorvastatin calcium requirements. Those prices were substantially greater than the prices that members of the Class would have paid absent the illegal conduct alleged herein, because: (1) the price of brand-name Lipitor was artificially inflated by Defendants' illegal conduct and/or (2) Class members were deprived of the opportunity to purchase lower-priced generic versions of Lipitor sooner.

212. As a consequence, Plaintiff and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

X. CLASS ACTION ALLEGATIONS

213. Plaintiff, on behalf of itself and all Direct Purchaser Class members, seeks damages, measured as overcharges, trebled, against Defendants based on allegations of anticompetitive conduct in the market for Lipitor and AB-rated generic equivalents.

214. Plaintiff brings this action on behalf of itself and, under Fed. R. Civ. P. 23(a) and (b)(3), as representatives of a Direct Purchaser Class defined as follows:

> All persons or entities in the United States and its territories who purchased and/or paid for or will pay for Lipitor and AB-rated generic equivalents in any form directly from Pfizer at any time during the period March 25, 2010 through and until the anticompetitive effects of defendants' conduct cease (the "Class

> Period"). For purposes of the Direct Purchaser Class definition, persons and entities purchased Lipitor and AB-rated generic equivalents if they paid some or all of the purchase price directly to any Defendant.

Excluded from the Direct Purchaser Class are Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all governmental entities.

215. Members of the Direct Purchaser Class are so numerous that joinder is impracticable. Plaintiffs believe that the Class numbers in the hundreds. Further, the Direct Purchaser Class is readily identifiable from information and records that are required by law to be maintained by pharmacies, drugstores, pharmaceutical benefit managers, and managed care organizations, as well as from records in the possession of the Defendants.

216. Plaintiff's claims are typical of the claims of the members of the Direct Purchaser Class. Plaintiff and all members of the Class were damaged by the same wrongful conduct of Defendants, *i.e.*, they paid artificially inflated prices for atorvastatin calcium and were deprived of the benefits of competition from cheaper generic versions of Lipitor as a result of Defendants' wrongful conduct.

217. Plaintiff will fairly and adequately protect and represent the interests of the Direct Purchaser Class. The interests of the Plaintiff are coincident with, and not antagonistic to, those of the Direct Purchaser Class.

218. Plaintiff is represented by counsel who is experienced and competent in the prosecution of class action antitrust litigation, and has particular experience with class action antitrust litigation involving pharmaceutical products.

219. Questions of law and fact common to the members of the Direct Purchaser Class predominate over questions that may affect only individual Class members because Defendants have acted on grounds generally applicable to the entire Direct Purchaser Class thereby making

overcharge damages with respect to the Direct Purchaser Class as a whole appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

220. Questions of law and fact common to the Direct Purchaser Class include:

a. whether Defendants willfully obtained and/or maintained monopoly power over Lipitor and its generic equivalents;

b. whether Defendants improperly listed the '995 patent in the Orange Book;

c. whether Defendants unlawfully excluded competitors and potential competitors from the market for Lipitor and its AB-rated generic bioequivalents; and

d. whether Defendants unlawfully delayed or prevented generic manufacturers from coming to market in the United States;

e. whether Defendants maintained monopoly power by delaying generic entry;

f. whether the law requires definition of a relevant market when direct proof of monopoly power is available, and if so the definition of the relevant market;

g. whether the activities of Defendants as alleged herein have substantially affected interstate commerce;

h. whether, and to what extent, Defendants' conduct caused antitrust injury (*i.e.*, overcharges) to Plaintiffs and the members of the Class; and

i. the quantum of aggregate overcharge damages to the Class.

221. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

222. Plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

XI. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
MONOPOLIZATION BY PFIZER UNDER 15 U.S.C. § 2

(Against Defendant Pfizer)

223. Plaintiff incorporates by reference the preceding allegations.

224. Pfizer knowingly and intentionally engaged in an anticompetitive scheme designed to block and delay entry of atorvastatin calcium, *i.e.,* AB-rated generic versions of Lipitor, and willfully to maintain their monopoly power. This scheme included (i) obtaining by actual fraud the '995 Enantiomer Patent (ii), fraudulently listing the '995 Enantiomer Patent in the FDA Orange Book, (iii) filing infringement litigation against multiple generic companies claiming infringement of the fraudulently obtained '995 Enantiomer Patent, (iv) fraudulently obtaining reissuance of the '995 Patent, (v) unlawfully agreeing with Ranbaxy to divide a market and delay price reductions for Lipitor, and (vi) otherwise engaging in an overarching scheme to unlawfully monopolize and conspire to monopolize the market for atorvastatin calcium.

225. By this scheme, Pfizer intentionally and wrongfully maintained their monopoly power with respect to atorvastatin calcium in violation of Section 2 of the Sherman Act. As a result of this unlawful maintenance of monopoly power, Plaintiff and members of the Class paid artificially inflated prices for their atorvastatin calcium requirements.

226. Plaintiff and members of the Class have been injured in their business or property by Pfizer's antitrust violations. Their injury consists of having paid, and continuing to pay, higher prices for their atorvastatin calcium requirements than they would have paid in the absence of those violations. Such injury, called "overcharges," is of the type antitrust laws were

designed to prevent, flows from that which makes Pfizer's conduct unlawful, and Plaintiff and the Class are the proper entities to bring a case concerning this conduct.

SECOND CLAIM FOR RELIEF
CONSPIRACY TO RESTRAIN COMPETITION IN VIOLATION OF 15 U.S.C. § 1

(Against Defendants Pfizer and Ranbaxy)

227. Plaintiff incorporates and realleges the preceding paragraphs.

228. Beginning in or about March of 2008, Pfizer and Ranbaxy engaged in a continuing illegal contract, combination and conspiracy in restraint of trade, the purpose and effect of which was to:

(a) allocate all sales of atorvastatin calcium in the United states to Pfizer;

(b) prevent the sale of a generic version of atorvastatin calcium in the United States until at least November 30, 2011, thereby protecting Lipitor from any generic competition for up to 20 months; and

(c) fix the price at which Plaintiff and the other members of the Class would pay for Lipitor at the higher, branded price.

229. By entering into these unlawful conspiracies, Defendants have unlawfully conspired in restraint of trade and committed a violation of Section 1 of the Sherman Act, 15 U.S.C. §1. Defendants' agreements are horizontal market allocation and price fixing agreements between actual or potential competitors and thus are per se violations of Section 1. In the alternative, Defendants' agreements are unreasonable restraints of trade in violation of Section 1 when viewed under a "quick look" or "rule of reason" mode of analysis.

230. Plaintiff and all members of the Class have been injured in their business and property by reason of Defendants' unlawful contract, combination and conspiracy. Plaintiff and the Class members have paid more on their purchases of Lipitor than they would have paid

absent Defendants' illegal conduct, and/or were prevented from substituting a cheaper generic alternative for their purchases of the more expensive Lipitor.

231. As a result of Defendants' illegal conduct, Plaintiff and the Class paid more than they would have paid for atorvastatin calcium, absent Defendants' illegal conduct. But for Defendants' illegal conduct, competitors would have begun marketing generic versions of atorvastatin calcium well before November 30, 2011, and/or would have been able to market such versions more successfully.

232. If manufacturers of generic atorvastatin calcium entered the market and competed with Lipitor in a full and timely fashion, Plaintiff and other Class members would have substituted lower-priced generic atorvastatin calcium for the higher-priced brand name Lipitor for some or all of their atorvastatin calcium requirements, and/or would have paid lower prices on some or all of their remaining Lipitor purchases.

233. During the relevant period, Plaintiff and the other Class members purchased substantial amounts of Lipitor directly from Pfizer. As a result of Pfizer's illegal conduct, alleged herein, Plaintiff and the other Class members were compelled to pay, and did pay, artificially inflated prices for their atorvastatin calcium requirements. Plaintiff and the other Class members paid prices for atorvastatin calcium that were substantially greater than the prices they would have paid absent the illegal conduct alleged herein because: (1) Class members were deprived of the opportunity to purchase lower-priced generic atorvastatin calcium instead of expensive brand name Lipitor; (2) Class members were forced to pay artificially inflated prices for generic atorvastatin calcium; and/or (3) the price of brand name Lipitor was artificially inflated by Defendants' illegal conduct.

XII. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiff, on behalf of itself and the Direct Purchaser Class, respectfully demand that this Court:

A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Class and declare the Plaintiffs representatives of the Direct Purchaser Class;

B. Enter joint and several judgments against Defendants in favor of Plaintiff and the Direct Purchaser Class;

C. Adjudge and decree the acts alleged herein, pursuant to Fed. R. Civ. P. 57 and 18 U.S.C. § 2201(a), to be an unlawful restraint of trade in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §2;

D. Award the Direct Purchaser Class damages (*i.e.*, three times overcharges) in an amount to be determined at trial;

E. Award Plaintiff and the Direct Purchaser Class their costs of suit, including reasonable attorneys' fees as provided by law; and

F. Grant such other further relief as is necessary to correct for the anticompetitive market effects caused by the unlawful conduct of Defendants, and as the Court deems just.

XIII. JURY DEMAND

Pursuant to Fed. Civ. P. 38, Plaintiff on behalf of itself and the proposed class demand a trial by jury on all issues so triable.

Dated: November 21, 2011

Respectfully submitted,

Thomas M. Sobol (BBO # 471770)
David S. Nalven (BBO # 547220)
Kristen Johnson Parker (BBO # 667267)
HAGENS BERMAN SOBOL SHAPIRO LLP
55 Cambridge Parkway
Suite 301
Cambridge, MA 02142

Don Barrett
DON BARRETT, P.A.
P.O. Box 987
404 Court Square North
Lexington, MS 39095
(admission *pro hac vice* to be requested)

Counsel for Professional Drug and the proposed Class